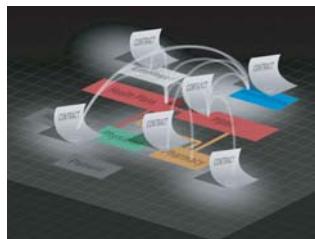


December 3, 2004



An Orientation to the Acquisition of and Reimbursement for Prescription Drugs

Script for DVD Tutorial Submission
of the Track One Defendants

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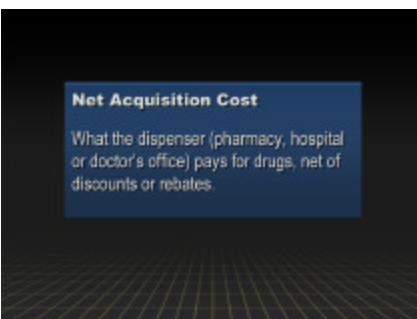
I Introduction



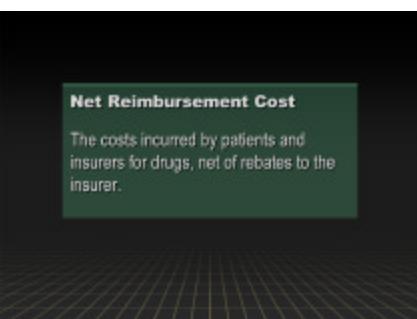
This is an orientation to the acquisition of and reimbursement for prescription drugs. My name is Dr. Fiona Scott Morton. I'm a professor of economics at the Yale School of Management. Over the past 13 years, one of my primary research interests has been the economics of competition in the pharmaceutical industry. With the help of this DVD, I hope to aid the court in gaining a deeper understanding of the complex interactions between parties and market forces that affect the prices paid and the amounts reimbursed when a patient gets a prescription filled. This tutorial will focus on the pharmaceutical industry during the period of interest in this case, beginning in 1991.



First, please allow me to introduce my colleague, Dr. Greg Bell, who will be appearing before your honor:



Thank you Dr. Scott Morton. Your Honor, for the past 12 years I've led the Pharmaceuticals practice at Charles River Associates, an economics and management consulting firm. In my capacity as a strategy consultant, I've led many projects involving pricing and contracting strategy in the pharmaceuticals industry.



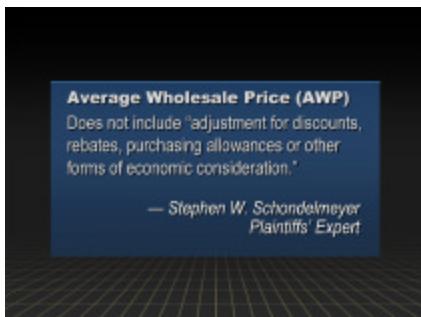
In my experience, there are two basic concepts that are key to understanding and comparing transactions in the pharmaceuticals marketplace:

First, Net acquisition costs. These are the costs that the dispenser—meaning a pharmacy, a hospital, or even a doctor's office—pays to acquire the drugs they dispense. These costs are net of any discounts or rebates to the dispenser.

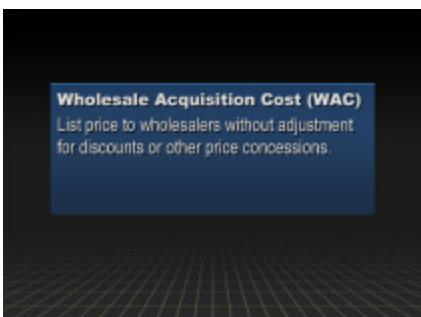
Second, net reimbursement costs. These are the costs that are ultimately incurred by the patients and their insurers for the drugs dispensed, net of any rebates to the insurer.



Spread is the difference between net acquisition cost and net reimbursement cost. Spread is a colloquial term that can refer to differences between cost and reimbursement at various points in the distribution and reimbursement chain.



There are many pricing and contracting terms that are used in various ways within the pharmaceutical and insurer industries. One such term is Average Wholesale Price or AWP. There is no regulatory definition of AWP. Historically, AWP was associated with the relationship between drug wholesalers and retail pharmacies. During the period of interest in this case, however, AWP has generally been used by insurers and other third-party payors simply as one of several reimbursement benchmarks.



One thing about AWP that is generally understood in the industry, including by a plaintiffs' expert in this case, is that AWP "does not include adjustments for discounts, rebates, purchasing allowances or other forms of economic consideration"¹ that might be given to a dispenser of the drug. Thus, AWP does not purport to represent any dispenser's actual acquisition costs, let alone an average of such costs.

Throughout this tutorial, we will explain the role AWP does and does not play in pricing and reimbursing drugs.

Another key term is Wholesale Acquisition Cost, or WAC. WAC is generally understood to be a list price to wholesalers, again without adjustment for discounts or other price concessions.

AWP is generally higher than WAC, often by a given ratio such as 1.2 or 1.25 for brand-name drugs, although the ratio can

¹ Declaration of Stephen W. Schondelmeyer in Support of Plaintiffs' Motion for Class Certification, September 2, 2004, paragraph 79, p. 32.

vary. AWP is generally published by commercial price reporting services such as the Red Book, which may also report WAC. Different price reporting services sometimes publish different AWPs for the same drug.

In the next section, we'll discuss the factors influencing acquisition and reimbursement cost and thus the factors that determine the spread.

II Factors Influencing Acquisition and Reimbursement Costs



A. Acquisition Overview

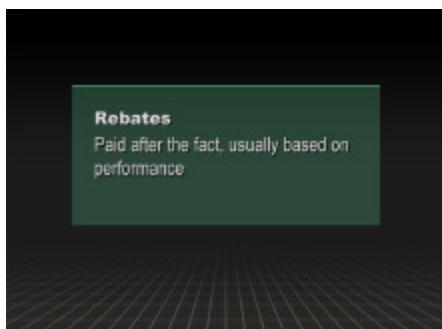
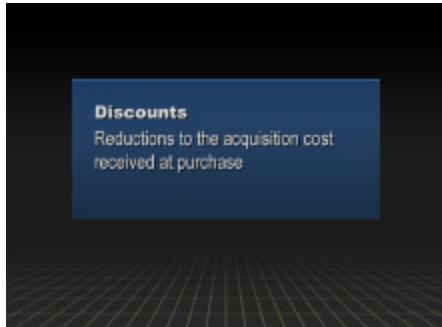
Let's begin by taking a look at how drugs are distributed and how they are paid for. We will introduce the industry players, the system that determines net acquisition costs, and the systems that determine net reimbursement costs.

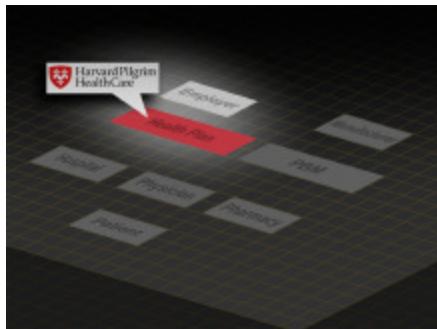
This graphic illustrates how drugs are acquired by dispensers such as pharmacies, hospitals and physician practices.

Prescription drugs typically move from the drug manufacturer, to a wholesaler or other intermediary (like a specialty physician supplier), to the dispenser. Sometimes drug manufacturers sell directly to the dispenser, which may be a pharmacy, a hospital or a physician. Dispensers acquire the drugs and dispense or administer them to patients.

Net acquisition cost is the price paid by the pharmacy, physician or hospital, net of discounts and rebates. Discounts are reductions to the acquisition cost that are received at purchase or indicated on the invoice, for instance, a 2% discount for prompt payment. Rebates are paid after the fact, perhaps quarterly, and are generally based on performance, perhaps total volume for the quarter.

As I will discuss in Section III, the net acquisition cost for a given drug can vary widely depending on a number of factors, including, significantly, the type of purchaser dispensing the drug.

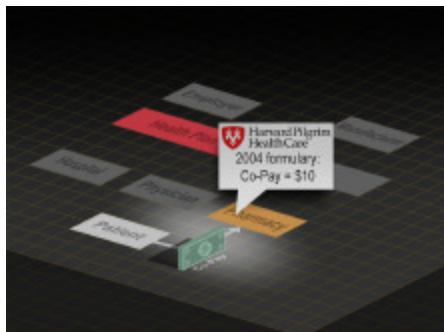




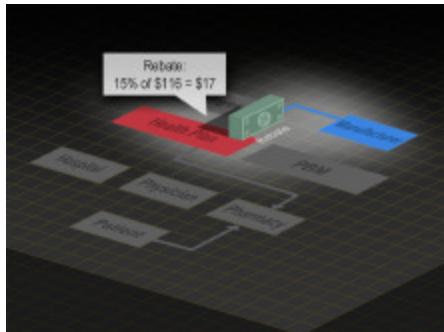
B. Reimbursement Overview

The situation becomes even more complicated when it comes to reimbursing the dispenser.

Let's consider the most common situation, someone who works for an employer who uses a managed care organization, say Harvard Pilgrim Health Care, to provide health care benefits. This might be a patient suffering from high cholesterol; so, the doctor writes a prescription for a brand name cholesterol lowering drug, a statin. The patient takes the prescription to a drug store, such as CVS, to be filled.



At the drug store, the pharmacist checks the patient's insurance to see how much the patient is supposed to pay. According to the patient's Harvard Pilgrim formulary for 2004, the patient is to pay \$10 for this drug.² This is the co-payment, or co-pay for short.



CVS receives the rest of its compensation for dispensing the drug from the patient's insurer. For brand-name patented products like this one, suppose that the contract between CVS and Harvard Pilgrim, states that Harvard Pilgrim will reimburse at the AWP of the product less 15%, less the patient co-pay, plus a dispensing fee.

In October 2004, the RedBook AWP for this drug was \$145.³ So, CVS collects \$10 from the patient and \$145 less 15% less \$10, or \$113, plus the dispensing fee, from Harvard Pilgrim. Thus, the total reimbursement that CVS receives is \$123, plus the dispensing fee.

² Harvard Pilgrim Pharmacy, *Drug Tier Lookup*, http://www.harvardpilgrim.org/portal/page?_pageid=253,41776&_dad=portal&_schema=PORTAL (accessed November 24, 2004).

³ Average Wholesale Price (AWP) for 30-day supply of a brand name statin 40 mg dose, as published by RxAdvantage, <https://www.ipcrx.com/>, citing *Red Book*, Thompson, October 2004.



Finally, let's suppose that Harvard Pilgrim had obtained a rebate from the manufacturer in exchange for granting exclusivity, in other words, being the only statin, or cholesterol reducing drug, available to its members for a \$10 co-pay. Other statins are available only if members make a higher \$25 co-pay.

To be the preferred statin on Harvard Pilgrim's formulary, or list of preferred drugs, the manufacturer might have agreed to pay Harvard Pilgrim a rebate equal to a certain percentage of all of this drug that Harvard Pilgrim reimburses each quarter. In this case, the rebate contract might specify that the manufacturer owes Harvard Pilgrim a rebate equal to 15% of the WAC or wholesale acquisition cost of the drug.

In October 2004, the WAC for this drug was \$116.⁴ So, Harvard Pilgrim receives a rebate from the manufacturer equal to 15% of \$116 or \$17.

So, what is the net reimbursement cost of this prescription? Well, it is the \$10 that the patient pays CVS, plus the \$113 that Harvard Pilgrim pays CVS, less the \$17 that Harvard Pilgrim received from the manufacturer equaling a total net reimbursement of \$106.

What is the spread on this prescription? Well, assuming that CVS acquires the the drug for the wholesale acquisition cost of \$116, it is this acquisition cost minus the net reimbursement cost of \$106, which equals a spread of negative \$10. In other words, the net reimbursement for this prescription (the net amount paid by the patient and the insurer) is \$10 less than what CVS actually paid to acquire the product.

⁴ Wholesale Acquisition Cost (WAC) for 30-day supply of a brand name statin 40 mg dose, as published by RxAdvantage, <https://www.ipcrx.com/>, citing *Red Book*, Thompson, October 2004.



There are a number of things to notice in this example:

First, AWP is only used as a benchmark, to which Harvard Pilgrim applies a 15% discount, with the resulting amount being Harvard Pilgrim's gross reimbursement to CVS.

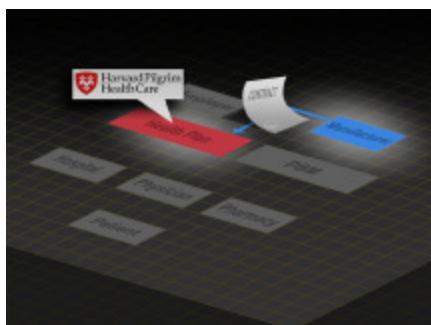
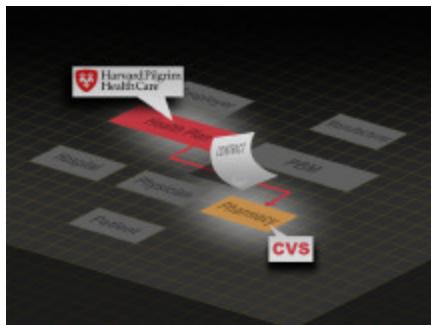
Second, the rebate from the manufacturer to Harvard Pilgrim, from the manufacturer to the insurer, reduces the insurer's net reimbursement cost and thus reduces the spread.

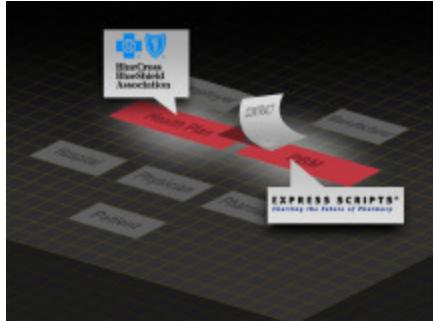
Third, the calculation of net reimbursement cost, and who is responsible for paying it, represents the result of several separate negotiations:

1. between the patient's employer and Harvard Pilgrim to determine the patient's co-pay amount;
2. between Harvard Pilgrim and CVS to determine the gross reimbursement amount or the total amount that CVS will receive and how that amount is to be split between reimbursement for the drug and reimbursement for the pharmacist's services including dispensing the drug and reviewing product information with the patient; and
3. between Harvard Pilgrim and the manufacturer to determine the amount of the rebate.

Of course, all of these negotiated terms could be subject to annual change and will vary by individual, including whether or not a particular patient receives pharmacy benefits from Harvard Pilgrim, a different insurer, or not at all; whether the plan allows members to fill prescriptions at CVS, and whether the plan prefers this drug on its formulary and therefore extracts a rebate from the manufacturer.

As another example, consider that this patient's neighbor may work for a different employer, such as Charles River Associates which uses Blue Cross Blue Shield of Massachusetts for health care benefits. Blue Cross Blue Shield of Massachusetts uses





Express Scripts, an independent pharmaceutical benefits manager or PBM, to help manage its coverage for pharmaceuticals.⁵

The PBM then becomes another link in the reimbursement chain, and there will be yet another negotiation to consider - this one between Blue Cross Blue Shield as insurer and Express Scripts as the PBM to determine how Express Scripts will be reimbursed for providing a negotiated set of services for Blue Cross Blue Shield. In fact, PBMs are involved in the vast majority of commercial drug reimbursement transactions.⁶

We refer to spread as the difference between the net acquisition cost to the dispenser and the net reimbursement cost for the payor. Both the net acquisition cost and net reimbursement amount are subject to several negotiations, which vary depending on the drug in question. The parties and their objectives vary as do the formularies that influence which drugs are prescribed. As a result, the spread will also vary transaction by transaction.

Recall that in our example, the rebates paid by the manufacturer to Harvard Pilgrim work to lower the net reimbursement and thus reduce the spread.

Other kinds of rebates and discounts can increase the spread. This is the case, when, for example, competing manufacturers of generic products offer discounts to a pharmacy to encourage it to stock their version of a generic drug. These discounts work to lower the pharmacy's acquisition cost and thereby increase

⁵ Blue Cross Blue Shield of Massachusetts, *Pharmacy Program*, http://www.bcbsma.com/pharmacy/en_US/pharmacyIndex.jsp (accessed November 23, 2004).

⁶ Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification ("Young declaration"), paragraph 104, citing the Federal Trade Commission and the Department of Justice's report, *Improving Health Care: A Dose of Competition*, July 2004, Chapter 7, p. 11.

Spread Example: Branded Drug, No Price Concessions	
Dispenser	
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate	0
Net reimbursement	108
Spread	8

Spread Example: Branded Drug, No Price Concessions	
Dispenser Gross Margin	
Reimbursement	108
Net acquisition cost	100
Gross margin	8
Manufacturer Net Proceeds	
Initial sale	100
Price concessions	0
Net proceeds	100

the spread. As we will see later in Section V, however, other reimbursement mechanisms typically come into play in the generic market to substantially reduce that spread.

C. Examples of Spread

So, let's consider a simple example to illustrate this concept of spread [see Appendix-Exhibit 1]. Let's first assume that the same branded drug is acquired by either a retail pharmacy or a physician, and that the manufacturer makes no price concessions to either. In this example, it won't matter who the dispenser is. Next, we will consider a case in which the manufacturer does make price concessions. In that case, the dispenser will matter a great deal.

So, assume a pharmacy or a physician acquires a branded drug directly from a manufacturer for \$100, which is the WAC for the drug. In this case, there are no price concessions from the manufacturer, no rebates or discounts; so, the net acquisition cost is \$100.

Next, on the reimbursement side, let's assume the insurer has negotiated with the pharmacy (or the physician) to pay reimbursement at AWP minus 10%. Let's assume that AWP for this drug is \$120. So, the insurer pays \$120 less 10% for \$108. The manufacturer does not pay any rebate to the insurer, so the net reimbursement is just that, \$108.

Here, the spread is \$8, the difference between the net acquisition cost and the net reimbursement. Note that in this example, net acquisition cost is lower than the net reimbursement.

Now, what was the gross margin on this transaction for the dispenser? Here, it is the same amount as the spread, \$8.

And what were the proceeds to the manufacturer? Well, the manufacturer initially sold the drug for \$100. Since there was no

Spread Example: Branded Drug, Retail Pharmacy, \$20 Manufacturer Rebate	
Dispenser	Retail
Acquisition cost (WAC)	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement (WAC - 10%)	108
Mfr rebate (to insurer)	20
Net reimbursement	88
Spread	-12

discount to the dispenser, and no rebate to the insurer, the manufacturer's net proceeds are just that, \$100.

Now, let's look at the case where the manufacturer makes a price concession of, let's say, \$20 [see Appendix-Exhibit 2].

In the retail pharmacy example, this concession could be in the form of a rebate to the insurer, typically as the result of a negotiation between the insurer and the manufacturer regarding a preferred position for the manufacturer's drug on the insurer's formulary. There would still be no discount to the dispenser.

Let's assume the manufacturer and the insurer have negotiated a rebate of 20% of WAC for this drug, which in this case is \$20. How does this impact the spread? Well, the rebate lowers the insurer's net reimbursement from \$108 to \$88. Consequently, the spread becomes negative \$12. In this case, the net reimbursement is lower than the net acquisition cost.

From the standpoint of the pharmacy, nothing has changed. The gross margin on the transaction remains \$8. But the manufacturer's proceeds have now dropped from \$100 to \$80, the difference being the \$20 rebate paid to the insurer.

Spread Example: Branded Drug, Retail Pharmacy, \$20 Manufacturer Rebate	
Dispenser Gross Margin	Retail
Reimbursement	108
Net acquisition cost	100
Gross margin	8
Manufacturer Net Proceeds	
Initial sale	100
Rebate	20
Net proceeds	80

Spread Example: Branded Drug, Physician, \$20 Manufacturer Discount	
<u>Dispenser</u>	<u>Physician</u>
Acquisition cost (NAC)	100
Mfr discount	20
Net acquisition cost	80
<u>Insurer</u>	
Reimbursement (NRP - 10%)	108
Mfr rebate (to insurer)	0
Net insurer reimbursement	108
<u>Spread</u>	<u>28</u>

What would happen if the drug here were acquired by a physician? Here, the price concession could come in the form of a discount to the physician. It would decrease the physician's acquisition cost by \$20, from \$100 to \$80.

Spread Example: Branded Drug, Physician, \$20 Manufacturer Discount	
<u>Dispenser Gross Margin</u>	<u>Physician</u>
Reimbursement	108
Net acquisition cost	80
Gross margin	28
<u>Manufacturer Net Proceeds</u>	
Initial sale	100
Price concession	20
Net proceeds	80

There would be no rebate paid to the insurer in this case, so the net reimbursement would remain at \$108. And now, the spread is \$28, with the net acquisition cost being lower than the net reimbursement. The dispenser, in this case a physician, realizes a gross margin of \$28, the same amount as the spread.

And what about the manufacturer? Well, the \$20 price concession to the physician has the same impact that the \$20 price concession to the insurer had in the earlier example – it lowers the manufacturer's net proceeds to \$80.



D. Three “Dimensions” Affecting Costs

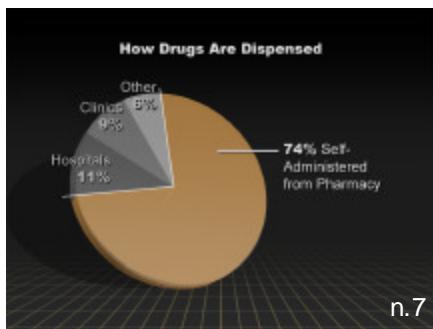
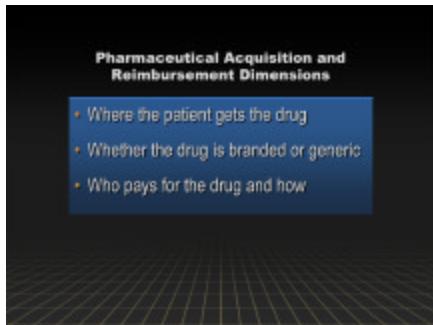
Now, let's return to our acquisition and reimbursement models. First, looking at the acquisition model, there are two factors that play a role in determining the net acquisition cost:

- where the patient obtains the drug, meaning a self-administered drug from a pharmacy, like the brand name statin we talked about earlier, or a physician-administered drug from a physician's office, like many cancer treatments; and,
- whether the drug is still patent-protected and therefore only available from the manufacturer, or generic, and therefore available from different manufacturers.

Then, referring to the reimbursement model, not only are these two factors important, but

- who pays for the drug—the government, a commercial third party like an insurer, or the patient him or herself—also makes a big difference in determining the amount of net reimbursement and how it is calculated.





Next, we'll discuss these three dimensions and why each one is important:

- where the patient gets the drug,
- whether the drug is branded or generic, and
- who pays for the drug and how net reimbursement cost is calculated.

E. Where the Patient Gets the Drug

Let's start with where the patient gets the drug. This matters for two reasons. In terms of acquisition, as we will explain, retail pharmacies typically acquire drugs at or slightly above WAC, while hospitals, in particular, may purchase at deep discounts. In terms of reimbursement, we will explain how the negotiation for physician reimbursement (the bundle of products and physician services) is very different than that for pharmacy reimbursement (which is product and dispensing services).

As you can see from this chart,⁷ here in the United States, most drugs are dispensed by pharmacies. Most drugs that a pharmacy carries will be self-administered, meaning the patient takes the drug on his or her own, without physician supervision.

The vast majority of the Track 1 defendants' drugs are self-administered⁸—they come as pills, capsules, patches, etc. Nexium from AstraZeneca and Claritin from Schering are probably familiar examples.

There are two primary types of pharmacies that dispense self-administered drugs.

⁷ IMS Health Inc, *IMS National Sales Perspectives*, August 2004.

⁸ *Amended Master Consolidated Class Action Complaint*, Appendix A, June 12, 2003, as cited in the *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification* ("Hartman declaration"), Table 1B.



The first type is the retail pharmacy, like CVS in our previous example. The second type is mail order pharmacy. To use a mail order pharmacy, patients request their prescriptions by mail, fax, phone or the Internet and later receive their drugs in the mail. Mail order pharmacies benefit from highly automated facilities in a central location that can ship to customers all over the country. Often, they ship 90-day supplies (rather than the typical 30-day supply), and send refill reminders, which help ensure that patients do not run out of their medications. Mail order pharmacies tend to be owned by either PBMs or national retail chains.⁹

Certain types of drugs are dispensed directly in the doctor's office. A patient might receive chemotherapy at her oncologist's office, for example Taxol from Bristol Myers Squibb could be used to treat breast cancer. While there, she might also receive an injection of Procrit from Johnson & Johnson used to help combat anemia.

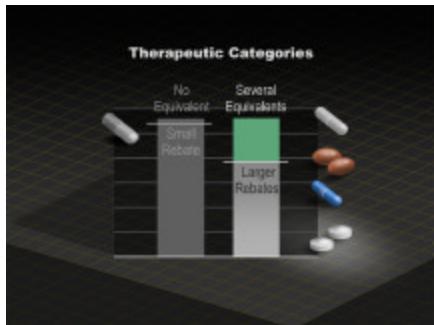
F. Branded v. Generic

The second factor that influences acquisition and reimbursement costs is whether the drug is "brand name", or generic.

Brand name drugs are those that are still subject to patent protection and fall into two distinct competitive categories:

There are drugs for which there are no direct therapeutic equivalents, in other words, no other drug which works in the same way. With no alternative drug, insurers, or the PBM that manages the insurer's formulary, are less able to extract a rebate from the manufacturer in return for a preferred position

⁹ Mercer Human Resource Consulting, *Navigating the Pharmacy Benefit Marketplace, a report prepared for the California Health Care Foundation*, January 2003, p. 6.



on the formulary. This was the situation, for instance, when Prilosec from Astra Zeneca, was introduced as the first proton pump inhibitor¹⁰ (a class of drugs that treat acid indigestion and reflux disease).



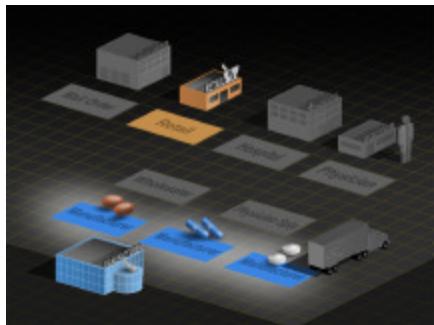
On the other hand, there are many therapeutic categories in which there are several similar branded products. Today, the proton pump inhibitor category includes Prevacid from TAP, AcipHex from Johnson & Johnson, Protonix from Wyeth, and Nexium from Astra Zeneca.

In this situation, insurers or their PBMs can influence product choice by designating certain products as preferred on their formularies. As I briefly mentioned earlier, formularies are lists of drugs insurers, or their PBMs, create, like the list in this booklet that Blue Cross Blue Shield of Massachusetts distributes to its members. Formularies specify the patient co-pay amounts for different drugs and dictate whether or not certain prior authorization steps need to be taken before a particular drug should be prescribed and dispensed to a plan member.

With this influence, the insurers or their PBMs can obtain rebates from the manufacturers. As we saw earlier with the example of the brand name statin, these rebates go to reduce the net cost of reimbursement and thereby reduce the spread.

Once a product is no longer patent protected, other manufacturers may obtain FDA approval to produce and sell a generic version of the product. These generic drugs incorporate the same chemical compound and are bioequivalent to the original product. Under certain circumstances, the Hatch-Waxman Act permits only one generic manufacturer to sell into

¹⁰ Mandy Leonard, Pharm.D., BCPS, "Esomeprazole (Nexium): A New Proton Pump Inhibitor," *Pharmacotherapy Update*, The Cleveland Clinic, Vol. IV, No. IV, July/August 2001.



pharmacies for the first six months after the patent expires.¹¹ After that, other generic manufacturers may enter.

When a patient brings in a prescription for a generic product, which manufacturer's version of the product is actually dispensed depends upon the pharmacy and which version it has chosen to carry. Typically, the pharmacy carries only one version of a generic drug. The generic manufacturers use price as one means of competing to be chosen by the pharmacy. The pharmacy obtains price concessions from manufacturers in the form of discounts or rebates, in return for carrying their versions of a generic.

Note that in these instances, the rebate or discount reduces the dispenser's acquisition cost and thus increases the spread.

The difference in the role of manufacturers' price concessions for branded versus generic drugs should be clear. For a branded drug, the competition centers on the doctor who writes a prescription specifying which branded drug is to be dispensed. So for the manufacturers of proton pump inhibitors, everything depends on which brand the doctor prescribes.

Accordingly, the insurers or their PBMs are able to extract rebates from the manufacturers to be one of or the only preferred proton pump inhibitor on the formulary. These rebates reduce the net reimbursement cost and thus reduce the spread.

In comparison, consider the example of Mevacor, another branded statin used in the treatment of high cholesterol, it's now available as generic lovastatin and sold by many manufacturers

¹¹ 21 CFR Part 60, Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).



such as: Carlsbad, EON, Genpharm, and several others.¹² For these firms, the competition focuses on being the generic on the shelf when the pharmacist reaches to fill a prescription for lovastatin.

Accordingly, the pharmacy is able to extract discounts from the manufacturers vying to be that generic lovastatin on its shelf. These discounts reduce the net acquisition cost and thus increase the spread.

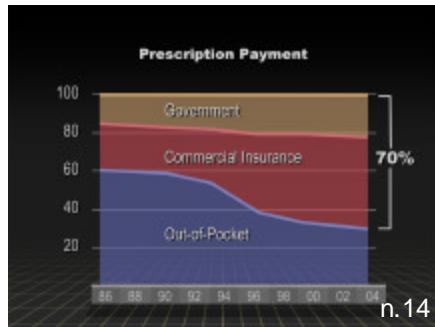
Insurers, of course, are not ignorant of this. Accordingly, when insurers negotiate with pharmacies regarding reimbursement rates, there is typically one set of rates, often using AWP as a benchmark, negotiated to cover patent-protected branded products and a separate set of rates, typically using Maximum Allowable Cost or MAC, negotiated to cover generic products. I'll discuss this further in Section V of this tutorial.

G. Who Pays and How

The third factor, but one which only influences reimbursement costs, is the identity of the payor. Sometimes a patient pays the full cost of a prescription at a pharmacy. In these instances, the patient may not have insurance for prescription drugs or may be covered under the older indemnity plans. It used to be that virtually all prescription drug insurance was offered on an indemnity basis – that is, the patient pays the full cost of a prescription at the pharmacy and then submits a claim to the insurer for reimbursement.¹³

¹² Food and Drug Administration (FDA), Lovastatin, <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=LOVASTATIN> (accessed November 22, 2004).

¹³ *Young declaration*, paragraph 66.



As you can see from the chart, patient “out of pocket” payments have been declining.¹⁴ Today, most people with prescription drug coverage are members of a managed care organization and pay only a portion of the cost of a prescription at the drug store. The payment is either a fixed amount co-payment, or it is a percentage of the total amount to be reimbursed, known as a co-insurance payment.



Following an insured patient’s purchase of a prescription, the dispenser presents a claim to a third party to receive the rest of the reimbursement. In 2002, seventy percent of the total U.S. expenditure on prescription drugs came from these third-party payors.¹⁵ These third-party payors can be classified broadly as government payors or commercial insurers. Each has different reimbursement approaches.

H. Government Payors

While there are several government programs that pay for prescription drugs, the only program relevant to this case is Medicare. Medicare is a government insurance program, established in 1965, to provide health care coverage for people over the age of 65, and for people with certain disabilities or with End Stage Renal Disease. As of 2002, Medicare had 39.6 million beneficiaries.¹⁶

There are two primary vehicles for Medicare coverage, traditional, or fee-for-service Medicare and Medicare + Choice,

¹⁴ Centers for Medicare and Medicaid Services (CMS), *Historical National Health Expenditures by Type of Service and Source of Funds*, <http://www.cms.hhs.gov/statistics/nhe/default.asp> (accessed November 23, 2004).

¹⁵ *Ibid.*

¹⁶ Kaiser Family Foundation (KFF), *Medicare Chartbook*, Fall 2003, p. 3.

or managed care. 88% of all Medicare recipients carry traditional Medicare coverage.¹⁷

For those who elect Medicare + Choice, their health care is managed by a commercial insurer in a plan similar to those offered to employers and groups. As such, those Medicare recipients who receive their pharmaceutical benefits coverage under a Medicare + Choice program are covered in the commercial insurance section of this tutorial.

Part B, Medicare's voluntary supplementary medical insurance, accounts for over one-third of Medicare benefit spending.¹⁸ It covers physician and outpatient hospital care, lab tests and other services, including "drugs administered incident to the provision of physician services" such as chemotherapy.¹⁹ Only a relatively small number of the Track 1 defendants' drugs are reimbursed under Part B.²⁰ These products include Taxol, an anti-cancer drug from Bristol Myers Squibb, and Procrit, an anemia treatment from Johnson & Johnson. When these drugs are dispensed to Medicare patients under Part B, reimbursement is governed by statute.

¹⁷ CMS, *Medicare+Choice Rates; Changes in Methodology Since 1999*, <http://www.cms.hhs.gov/healthplans/rates/2000/45day-03.asp> (accessed November 24, 2004).

¹⁸ KFF, *Medicare at a Glance Fact Sheet*, March 2004, Figure 1.

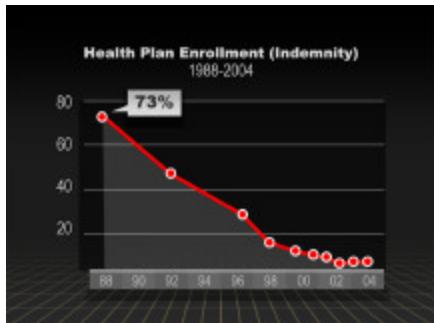
¹⁹ *Young declaration*, paragraph 159.

²⁰ 15 out of the 136 drugs mentioned in Appendix A of the *Amended Master Consolidated Class Action Complaint* are labeled as drugs administered in the outpatient setting, as shown in the *Hartman declaration*, Table 1B.



In a landmark change to the Medicare program introduced by last year's Medicare Modernization Act, Medicare will begin partial reimbursement for self-administered drugs in 2006 under Part D.²¹ It is expected that Part D will cover many of the other pharmaceuticals not covered by Part B.

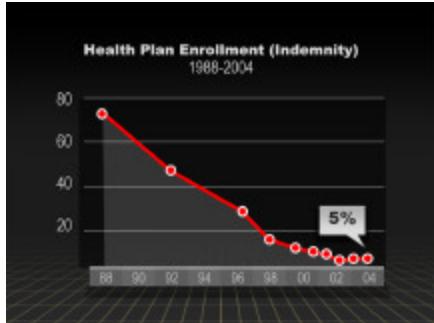
²¹ *Medicare Program; Medicare Prescription Drug Benefit*, Proposed Rules, 42 CFR Parts 403, 411, 417, and 423 [CMS-4068-P] RIN 0938-AN08, Federal Register, Vol. 69, No. 148, August 3, 2004.



I. Commercial Payors

By far, the most common type of third-party payor is a commercial insurer.²²

An employer deals with an insurer to offer a health plan as a part of an employee benefits package. The health plan offers certain defined medical and drug benefits to employees, their dependents, retirees and any other group members.



While today, most health plans are managed care plans, historically the indemnity model was used. While large insurers still offer indemnity plans, this type of coverage has declined from 73% of all covered employees in 1988, to only 5% in 2004.²³

During the 1980s, insurers began to develop ways of dealing with ballooning health care costs. For instance, insurers started asking their beneficiaries to accept limits on the choice of which doctors they could see and which hospitals and pharmacies they could use. In return, the insurers offered lower premiums. Requiring their members to use only “network” care givers, the insurers were able to negotiate reduced rates from the doctors, hospitals, and pharmacies in the plan’s network by promising higher patient volumes.

As noted earlier, health plans have developed other mechanisms for controlling drug costs. A formulary is a list of drugs covered by a patient’s health plan. Different tiers on the formulary correspond to different co-pay and co-insurance amounts. For instance, my health plan, as provided by my employer, CRA, through Blue Cross Blue Shield of

²² CMS, *Historical National Health Expenditures by Type of Service and Source of Funds*.

²³ KFF, *Employer Health Benefits 2004 Annual Survey*, Exhibit 5.1, p. 69.

Blue Cross/Blue Shield Formulary: Co-Pay Amounts	
Tier 3	\$35 Non-Preferred Brands
Tier 2	\$20 Preferred Brands
Tier 1	\$10 Generics

Massachusetts, uses a three-tier formulary.²⁴ I pay \$10 for prescriptions of drugs on the first tier, typically generics and including omeprazole, the generic version of Prilosec; \$20 for drugs listed on the second tier, typically preferred brands, including Protonix, a competing proton pump inhibitor offered by Wyeth; and \$35 for drugs listed on the third tier, which includes the non-preferred but covered or reimbursed drugs, including brand-name Prilosec.

Certain other products, such as Nexium, Astra Zeneca's new proton pump inhibitor, are not covered at all. If my physician writes a prescription for Nexium, I must pay the full price for that at the pharmacy. This formulary list is distributed by Blue Cross Blue Shield of Massachusetts to both the doctors in its network and its members, informing them which pharmaceuticals are preferred to be dispensed, and encouraging those drugs to be prescribed. Note that CRA's plan is only one of 14 basic plans offered by Blue Cross Blue Shield in Massachusetts alone.²⁵

The managed care model has become the predominant form of health insurance coverage, as evidenced by the number of individual lives now covered by managed care. In 2003, 174 million people in the U.S. had employer-sponsored health care.²⁶ In 2004, 95% of those employer-insured individuals were covered by some manner of managed care plan.²⁷

²⁴ Blue Cross Blue Shield of Massachusetts, Pharmacy Program, http://www.bcbsma.com/pharmacy/en_US/pharmacyIndex.jsp (accessed November 24, 2004).

²⁵ Blue Cross Blue Shield of Massachusetts, Home Page, http://www.bcbsma.com/common/en_US/index.jsp (accessed November 24, 2004).

²⁶ The United States Chamber of Commerce, *Facts on How Employers Support Their Workers*, August 2004, <http://www.uschamber.com/government/issues/labor/laborday.htm> (accessed November 30, 2004).

²⁷ KFF, *Employer Health Benefits 2004 Annual Survey*, p. 69.



There are many different types of health insurer, they include:

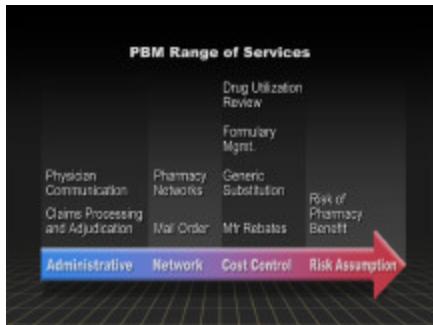
- the large, national for-profit companies like Cigna or Aetna, which offer a wide variety of coverage plans
- then, there are smaller, regional plans like Harvard Pilgrim, which offers a full line of coverage options but only covers Massachusetts, Maine and New Hampshire
- Blue Cross Blue Shield is an association of independent plans, each typically covering a specified geography, that share brand identity and administrative services.

Each of these insurers may offer different types of coverage: HMO, PPO, POS, etc. These vary based on the degree of choice that might be offered and the extent to which out-of-network services can be utilized. One special type is the staff model HMO. Kaiser Permanente is perhaps the most well-known of the staff model HMOs. These are health plans that integrate their own care delivery systems—the pharmacies and hospitals are owned by the HMO and the physicians are salaried employees of the HMO.

Some employers find it cost-effective to assume the risk of being their own insurance company. These companies (generally large firms like Wal-Mart, GM and Microsoft) become the direct payor for their employees' pharmaceutical reimbursements.²⁸ These employers usually hire third-party administrators (or TPAs) to handle claims processing and benefit management.

PBMs are available to provide pharmacy benefit management services to all insurers. These services can range from third-

²⁸ The National Council of Self-Insurers, *State Self-Insurer Associations Survey*, http://www.casef-insurers.com/NCSI_SI_ASSOC_SURVEY.htm (accessed November 24, 2004).



party administrator services such as claims processing to mail order services, formulary management services, and even the assumption of risk for the provision of pharmacy benefits.

Which services are provided and how the PBM is paid are the subject of negotiations between the insurer and the PBM.

PBMs may be owned by insurers, such as the relationship between Pacificare and its PBM, Prescription Solutions, providing their services to their parent and potentially offering their services to other insurers.²⁹ Other PBMs, such as Medco, are independent of the insurers that they serve.

So, we've identified the various parties that are involved in the acquisition and reimbursement of prescription drugs, and described three key factors which have a big impact on acquisition and reimbursement processes and outcomes - where the patient gets the drug, whether the drug is branded or generic, and who pays for the drug. Next, we'll look at how these factors interact to determine actual net acquisition costs and net reimbursements.

²⁹ Prescription Solutions is a wholly owned subsidiary of PacifiCare Health Systems, Inc. <http://www.rxsolutions.com/a/about/PRView.asp?doc=243> (accessed November 22, 2004).

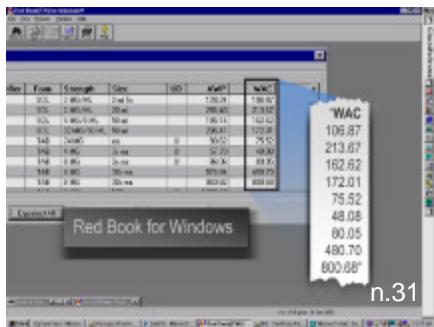
III Defining Acquisition Cost



Let's start by examining how retailers buy drugs.

A. Wholesalers

Manufacturers typically sell their branded, patent-protected, sole-source drugs, to wholesalers, who in turn distribute them to retail pharmacies, hospitals, and other medical facilities. Cardinal Health, McKesson Corp. and AmeriSource Bergen are the major drug wholesalers.³⁰



Manufacturers typically set a Wholesale Acquisition Cost, or WAC, which is the list price, not including discounts, at which they sell the product to wholesalers and to some other direct customers, such as mail order facilities. WAC is a price that many manufacturers provide to publishers of pharmaceutical pricing information, such as the Red Book.³¹

Wholesalers generally acquire sole-source brand-name products at WAC, minus a 2% "prompt pay" discount from the manufacturer if they pay promptly. Retailers, in turn, typically buy from wholesalers at an amount that may include a small markup for the wholesaler. Sometimes, the manufacturers distribute directly to the large retail chains that provide their own warehousing function.

³⁰ Eastern Research Group, Inc., *Profile of the Prescription Drug Wholesale Industry*, 2001.

³¹ WAC and AWP pricing for Zofran, price list expiration date October 31, 2003, Red Book Online for Windows, Vol. 29, Thompson, 2003.

B. Retail Pharmacies

There are two major differences when retail pharmacies buy generic drugs.

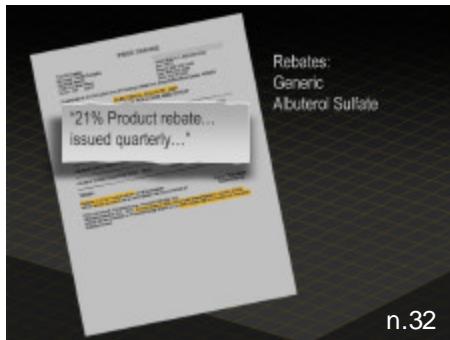
One, sales often bypass the wholesaler –generic manufacturers are more likely than branded manufacturers to deal directly with large pharmacy chains.

And two: generic manufacturers compete for pharmacy business, generally transacting at spot prices (prices at which their drugs can be bought at a specified time, and which vary frequently).

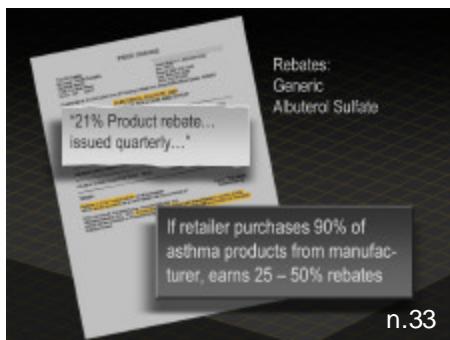
Why do these differences exist? Well, it's because the pharmacy determines which manufacturer's version of a particular generic will be dispensed. Therefore, the net acquisition cost of generics is typically based on negotiations between the pharmacy and manufacturers, and the discounts and rebates that the pharmacy is able to obtain.

The situation, of course, is different for patent-protected drugs. In those cases, the pharmacy can do little but dispense the product that was prescribed. So, when it comes to patent-protected products, the pharmacies have little ability to obtain discounts and rebates from the manufacturers.

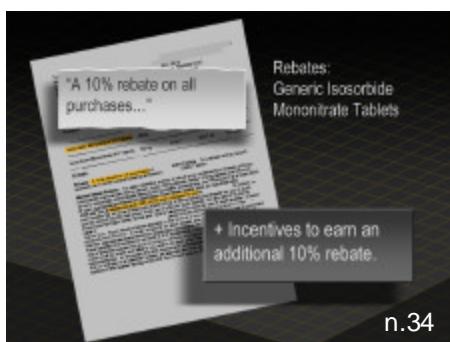
Depending upon the volume of business or the number of products carried, the generic manufacturer may offer the pharmacy a discount or rebate. This effectively lowers the



n.32



n.33



n.34

acquisition cost. In this example, for generic albuterol sulfate, a drug which treats asthma, the manufacturer offers two types of rebates. First, the retailer gets a 21% rebate, issued quarterly as a credit toward future purchases.³²

In addition, there are conditions under which the retailer can earn further rebates. If the retailer's purchases of albuterol combined with purchases of this manufacturer's other asthma products represent at least 90% of the retailer's purchases of total asthma products, then rebates of 25% to 50% are provided on the manufacturer's other asthma products.³³

In a separate agreement with the same retailer for a different generic drug, this same manufacturer offers a 10% rebate for all purchases of the drug, with incentives for an additional 10%.³⁴ These examples demonstrate a range of terms that can be negotiated, even between one pharmacy and one manufacturer for different products.

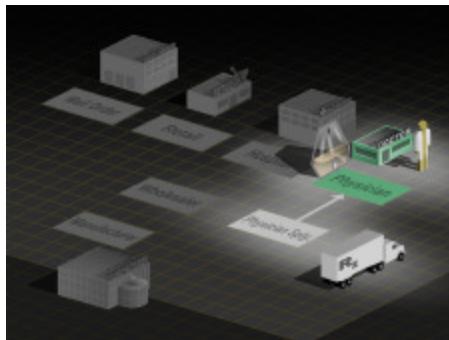
C. Mail Order Pharmacies

Mail order pharmacies are an increasingly important low-cost dispenser of pharmaceuticals. Mail order pharmacies use automated processes to remind patients to renew their prescriptions and contact physicians for permission to switch patients to preferred or generic drugs. Accordingly, payors often encourage their members to buy by mail. These features combine to give mail order pharmacies more leverage than retail pharmacies in obtaining discounts and rebates from manufacturers for both branded and generic drugs.

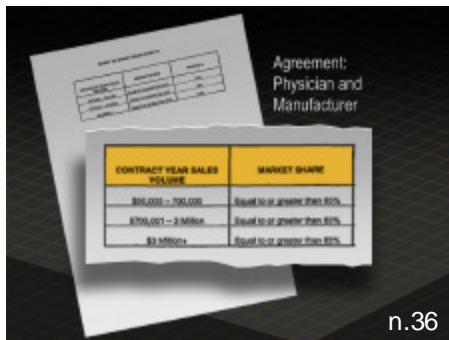
³² Price Change Memos, CTL00220269-279.

³³ *Idem*.

³⁴ Price Change Memos, CTL00111879-881.



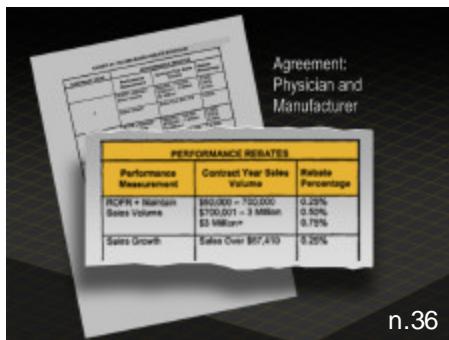
In some cases it is the payors themselves, through ownership of mail order or in-house pharmacies, that acquire the drugs. In 2002, a survey of 504 HMO's of varying types in the United States found that 19 percent of them owned pharmacies, and therefore were direct purchasers of pharmaceutical products.³⁵ These insurers negotiated the kinds of discount and rebate deals we have been discussing for the acquisition of pharmaceuticals.



So, for both retail and mail order pharmacies, discounts and rebates lower the pharmacy's acquisition cost, enabling them to compete by accepting lower reimbursement amounts from the payors, and thus lowering the cost of providing health care.

D. Physicians

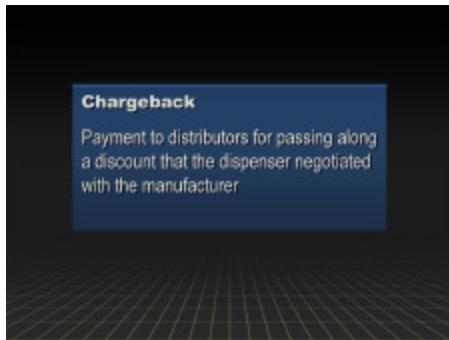
The other dispenser primarily at issue in the case is the physician practice when it is acquiring chemotherapy and other products that it dispenses. Physician practices, like pharmacies, also acquire drugs through wholesalers. But there are also specialty physician supply houses, such as Oncology Therapeutics Network or OTN, that provide an alternative distribution channel to deal with the special handling and higher costs associated with supplying these drugs to physicians.



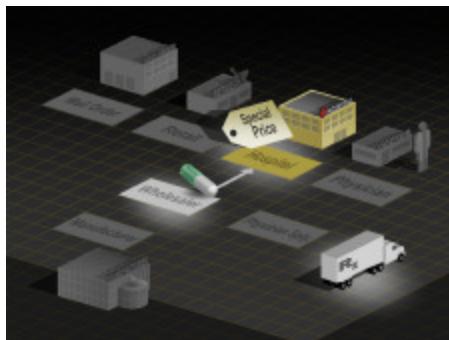
Because the physician can control which products are dispensed, the physician's practice or group can obtain preferred pricing, using either discounts or rebates, from the manufacturer, particularly when there is a choice among two or more therapeutic alternatives. This rebate agreement between a physician group and a manufacturer includes a range of rebate terms related to both sales volume and market share. And, the same manufacturer offers very different terms to another physician group, for the same product.³⁶

³⁵ Aventis Managed Care Digest Series, *HMO-PPO/Medicare-Medicaid Digest 2003* p. 6 and 37, <http://www.managedcaredigest.com/HMOPPO.jsp> (accessed November 23, 2004).

³⁶ Rebate Agreements, MDL - OBI 00026243 and MDL - OBI 00026289.



Since the physician is usually an indirect customer (that is, they acquire drugs through a physician supply house or wholesaler), the manufacturer may agree to reimburse the distributor for the difference between their cost and the discounted price negotiated with the physician. This type of payment is called a chargeback, and is the simplest way to pay back the distributors for passing along a discount that the physician has successfully negotiated from a manufacturer.



E. Hospitals

Hospitals typically purchase drugs the same way. Manufacturers may ship directly to hospitals, but often the hospitals are supplied by the wholesaler, at special prices that have been negotiated with the manufacturer. Like the products dispensed in a physician's office, the hospital is in a unique position to determine which products are prescribed and dispensed to inpatients. Accordingly, the hospitals can extract discounts from manufacturers for offering products a preferred position. These discounts are handled through the "chargeback" system.



Basically, the hospital negotiates a reduced price with the manufacturer in return for stocking certain products. The manufacturer informs the wholesaler of this special price for the hospital. The wholesaler transacts with the hospital at the special price and charges back to the manufacturer the difference between the special price and the regular price, typically WAC. In addition, the hospital may receive a quarterly rebate from the manufacturer based on reaching a given dispensing volume or ensuring that the preferred product realizes a certain share of the prescriptions within a therapeutic category.

So, in the case of physicians and hospitals, the discounts and rebates negotiated with the brand-name and generic manufacturers serve to reduce the net acquisition cost. Since

physicians and hospitals compete for patients and to be part of the networks used by insurers, the discounts and rebates they get, which lower their costs, allow them to accept lower reimbursement amounts offered by insurers, and thus lower the cost of providing health care.

The next two sections of our tutorial deal with reimbursement, first under Medicare Part B and then under a commercial insurance plan, which may or may not use a PBM.

IV Reimbursement Under Medicare Part B

First, we'll consider reimbursement under traditional Medicare Part B. But, remember, Part B reimburses only for certain products, mainly physician-administered drugs; and remember, Medicare + Choice recipients receive their Medicare benefits through commercial insurers and so the implications of reimbursement for their use of pharmaceuticals is covered in the next section of our tutorial. Unlike the various types of commercial reimbursement, which are defined in contracts, reimbursement for prescription drugs under traditional Medicare Part B is provided by statute.

Traditional Medicare reimburses on a fee-for-service basis. For services rendered in the physician's office, the physician bills Medicare directly for reimbursement based on the regulatory provisions, on a case-by-case basis.³⁷

A. Medicare Timeline

Let's look at how the reimbursement formulas have changed over time for patent-protected, branded drugs reimbursed under Part B.

Prior to 1992, Medicare reimbursed physicians based on a reasonable charge methodology.³⁸ The Medicare carriers were charged with determining the reasonableness of physicians' billed charges which specified procedures administered and drugs dispensed on a line-by-line basis.³⁹

³⁷ Department of Health and Human Services (DHHS), Office of Inspector General (OIG), *Medicare Reimbursement of Prescription Drugs*, Report # OEI-03-00-00310, January 2001, p. 1. as cited in *Young declaration*, paragraph 59.

³⁸ Social Security Act § 1833, 42 U.S.C. 1395l, as cited in *Young declaration*, Exhibit 16a.

³⁹ *Young declaration*, paragraph 160.

Since 1992, the reimbursement formula for Medicare has changed to specify an upper limit. Medicare still reimburses based on physician charges, but these are subject to upper limits for both the drug and the infusion and other services provided at the physician's office.⁴⁰

It is, of course, not known the extent to which the charges submitted by a particular physician's office are or are not based upon AWP. In order to determine whether a given physician's charges were based upon AWP, it would be necessary to obtain additional information from that physician.

In June 1991, as part of a general overhaul of how Medicare would pay for pharmaceuticals and physician services under Part B, the government proposed setting the maximum reimbursement for pharmaceuticals at 85% of AWP.⁴¹ However, comments were received from physicians claiming the 85% reimbursement standard would be inadequate because it would fail to provide enough margin to account for Medicare's proposed reductions in reimbursements for professional fees and office overhead costs.⁴²

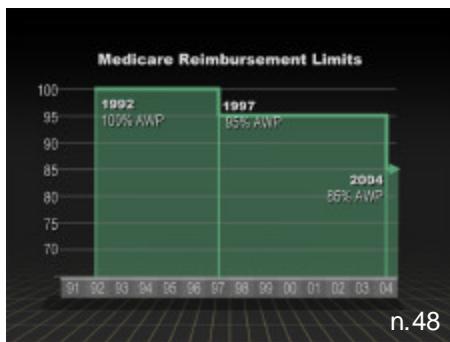
Therefore, in January 1992, a regulation issued setting the maximum reimbursement for pharmaceuticals under Medicare Part B at the lesser of either 100% of the national AWP, or the estimated acquisition cost as determined by surveys.⁴³ The surveys, however, were never conducted.

⁴⁰ *Ibid*, Exhibit 16a.

⁴¹ *Ibid*, paragraph 162.

⁴² House Ways And Means Committee, Subcommittee on Health, *Testimony of Thomas A. Scully, Administrator of the Centers for Medicare & Medicaid Services, On Reimbursement & Access to Prescription Drugs Under Medicare Part B*, October 3, 2002.

⁴³ DHHS, OIG, *Suppliers' Acquisition Costs For Albuterol Sulfate*, Report # OEI-03-94-00393, June 1996.



In November 1992, the Office of Inspector General of Health and Human Services reported that “AWP is not a reliable indicator of the cost of a drug to physicians,” finding that AWP was typically well in excess of physicians’ acquisition costs.⁴⁴

So, reimbursement of pharmaceuticals under Medicare Part B was set at the lower of submitted charges or 100% of AWP,⁴⁵ even though it was well understood that AWP-based reimbursements to doctors would provide them with significantly more than what they paid for the drugs they dispensed.⁴⁶

In 1997, Congress changed the reimbursement for drugs under Medicare Part B to the lower of actual amount billed by the physician or 95% of AWP.⁴⁷

Through September 2002, when the complaint in this action was filed, Medicare maintained reimbursement at those levels. Then, starting in 2004, maximum reimbursement was reduced again, in general to 85% of AWP.⁴⁸

Numerous reports show that throughout the 1990’s, both Congress and Medicare continued to be aware that Medicare Part B drug reimbursements were well in excess of acquisition costs, and were cross-subsidizing, or making up for, perceived Medicare under-reimbursements for physicians’ professional fees and clinic overhead costs.⁴⁹

⁴⁴ DHHS, OIG, *Physicians’ Costs for Chemotherapy Drugs*, Report # A-02-91-01049, November 6, 1992.

⁴⁵ *Young declaration*, Exhibit 16a.

⁴⁶ DHHS, OIG, *Physicians’ Costs for Chemotherapy Drugs*, Report # A-02-91-01049, November 6, 1992.

⁴⁷ *Young declaration*, paragraph 165.

⁴⁸ *Young declaration*, Exhibit 16a.

⁴⁹ *Young declaration*, paragraph 64 and Exhibit 7. The OIG recognized in 2001 that some physicians had become reliant on “inflated drug payments as a subsidy for their expenses”, as shown in the DHHS, OIG report *Comparing Medicare Physician Payments To Private Payors*, Report # OEI-06-00-00570, January 2003.



For physician-administered generic drugs, reimbursement under Part B has been based on the lesser of A) the median AWP for all sources of the generic form of the drug and B) the lowest AWP of branded forms of the drug.⁵⁰

B. Variability in Medicare Reimbursement

To process claims for reimbursement, Medicare contracts with various commercial insurance companies, such as the various Blue Cross Blue Shield plans. In 1991 there were 35 such Medicare carriers; today there are 17.⁵¹

Even though reimbursement is based on formulas, there is some variation in actual reimbursement amounts. According to a 2001 report, the OIG found that carriers were not establishing consistent reimbursement amounts for some drugs.⁵²

In addition, these carriers are permitted to exercise some discretion in reimbursement through “Local Medical Review Policies.”⁵³ These published policies provide guidance to physicians in the carrier’s coverage area, and explain how various items or services will be reimbursed. Some of these policies differ, creating variability in reimbursement levels.

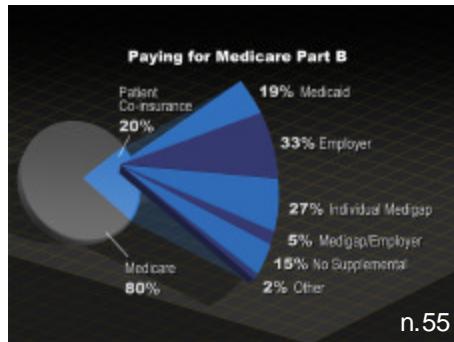
For instance, in 1997, the Medicare carrier for South Carolina established a local policy to reimburse for two different treatments for prostate cancer based on a concept called “least costly alternative”, or LCA. That means that reimbursement for one drug could not be higher than that for the other.

⁵⁰ CMS, *Medicare Claims Processing Manual*, Chapter 17, sec. 20.3, www.cms.hhs.gov/manuals/104.claims/clm104c17.pdf (accessed November 24, 2004).

⁵¹ *Young declaration*, Exhibit 16b.

⁵² DHHS, OIG, *Medicare Reimbursement of Prescription Drugs*, Report # OEI-03-00-00310, January 2001, p. 4.

⁵³ *Young declaration*, paragraph 171.



Accordingly, the carrier set the reimbursement amount for both Lupron and Zoladex, the drugs at issue, based on the AWP for the lower of the two. Since that time, forty additional states have set reimbursement policies based on LCA for Lupron and Zoladex at various points in time.⁵⁴

So, those are the rules as they relate to the definition of the maximum reimbursement permitted under Medicare Part B. Medicare is responsible for 80% of the reimbursed amount; and the patient is responsible for the remaining 20% as co-insurance. Most of the time, however, the patient does not pay the co-insurance him or herself; it is covered by another third-party payor.⁵⁵

The vast majority of Medicare beneficiaries (85% in 2000) have some form of supplementary insurance coverage, which provides reimbursement for some portion of the patient's 20% share.

Supplementary coverage may come from Medicaid, an employee benefit plan, or a separate "Medigap" policy purchased from a commercial insurer by the recipient.⁵⁶

There is a great deal of variation in the manner and extent to which these various types of supplementary coverage reimburse for the patients share of Part B expenses. Today, there are ten standard Medigap plans available.

To summarize, under traditional Medicare Part B, which covers most Medicare recipients, physician-administered drugs are

⁵⁴ *Idem.*

⁵⁵ DHHS OIG, *Medicare Reimbursement of Prescription Drugs*, Report # OEI-03-00-00310, January 2001, p. 1. as cited in *Young declaration*, paragraph 59.

⁵⁶ CMS, *Program Information on Medicare, Medicaid, SCHIP, and other programs of the Centers for Medicare & Medicaid Services*, June 2002, p. 9, <http://www.cms.hhs.gov/charts/series/sec3-b1.pdf> (accessed December2, 2004).

reimbursed according to statutes as administered by local Medicare carriers. The formulas specify reimbursement at the lesser of some percentage of AWP and another amount, usually the actual charges billed by the physician. Medicare covers 80%, the patient 20%. But most patients have other insurance to cover their share, and there is a great deal of variability among these policies.

Remember, throughout the time period at issue, and until 2006, most drugs used by Medicare patients were not covered by Medicare, and therefore the rules and regulations under Part B do not apply. With the enactment of the Medicare Prescription Drug, Improvement and Modernization Act or MMA of 2003, significant changes to drug reimbursement under Medicare will occur:

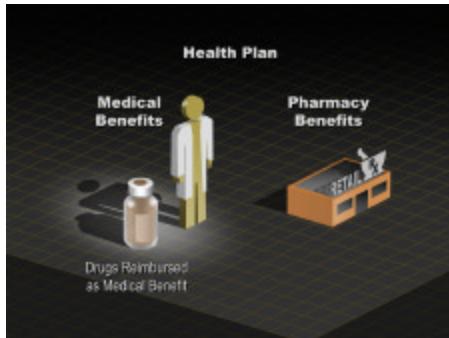
Beginning in January 2005, Medicare will again change its reimbursement for Part B drugs, using what the new statute calls an Average Sales Price, or ASP, which will be determined quarterly from a new drug price-reporting system. The standard payment rate for most Part B drugs will be set at 106 percent of ASP.⁵⁷ Again, recognizing that drug reimbursement had been subsidizing other physician services, service fees will generally be increased for 2005. For example, the payment for administration of a flu vaccine has increased from \$8 to \$18; and, the dispensing fee for inhalation drugs delivered by nebulizers has increased more than ten-fold, from \$5 to \$57.⁵⁸ Further, it is not even the case that drug reimbursement will decline in all cases under the new rules.

⁵⁷ CMS, *Medicare Program CMS 2004 Final Rule*, 42 CFR Part 414 [CMS-1380-F] RIN 0938-AN05.

⁵⁸ The Pink Sheet, *Inhalation Drugs Will Have \$57 "Transitional" Dispensing Fee in 2005*, Vol. 66, No. 045, p. 22, November 8, 2004.

It is important to note that drugs that are covered by Medicare Part B are often also covered, in some way, by commercial insurance plans. As discussed in the next section, there are many varieties of commercial insurance plans, and how they reimburse for these physician administered drugs—just as how they reimburse for other drugs—depends on a complex set of factors.

V Reimbursement under a Commercial Plan



We've just finished describing reimbursement by government payors under Medicare Part B. In this section we turn to reimbursement by commercial third-party payors.

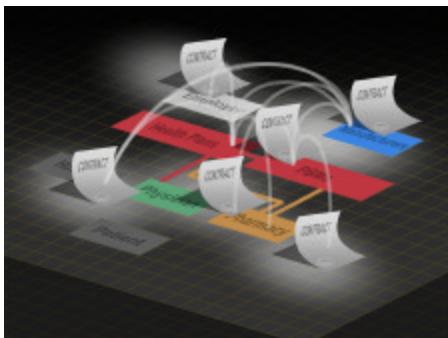
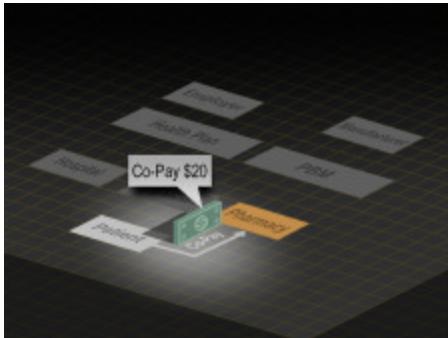
A. Drug Coverage under Medical and Pharmacy Benefits

Reimbursement for prescription drugs in the commercial setting applies to employers, group plans and Medicare-eligibles who have opted for Medicare benefits offered through managed care. While our discussion mainly refers to employers, the same principles and issues apply to unions and other entities insuring groups of individuals.

Most health plans typically include both medical benefits and drug benefits. Either one or two separate insurers may provide the two types of benefits. In some cases, certain drugs dispensed in the physician's office will be deemed a medical benefit and subject to reimbursement rules different from the self-administered drugs that typically fall under the pharmacy benefit.

Under the pharmacy benefit, the patient is required to pay the co-payment or co-insurance as required by the formulary for prescription drugs. Under a medical benefit, the amount the patient is required to pay is based on the plan's co-payment and co-insurance schedule for physician visits and other medical benefits.

As an example, consider the following situation. A commercially-insured cancer patient requires treatment for anemia. The patient receives chemotherapy at her physician's office and also an injection of Procrit. According to the contract between the patient's employer and the insurer, the patient might pay a \$15 co-pay for the visit, including the physician services, the chemotherapy drugs, and the Procrit. According to



the contract between the physician and the insurer, the physician bills the health plan to receive the remainder of the reimbursement.

Now, it may be appropriate for Procrit to be administered more frequently than the particular chemotherapy regimen that the patient is receiving. Accordingly, the patient may learn to self-administer Procrit. In this case, she must obtain Procrit from a pharmacy, and it would be covered as a pharmacy benefit. It might be that Procrit is reimbursed as a second-tier drug requiring that the patient make a \$20 co-payment to the pharmacy for the Procrit alone.

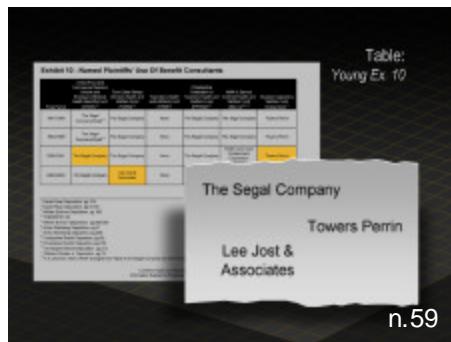
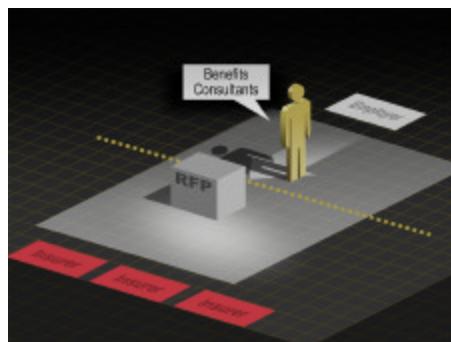
So, for some drugs, the same health plan might reimburse differently. Of course, even if different insurance plans classify a particular drug benefit the same way—either medical or pharmacy—the reimbursements for these products may be quite different.

B. Multiple Contracts Govern Reimbursement

In all circumstances, pharmaceutical reimbursement is defined by a series of contracts between the payor, often one or more intermediaries, and the pharmacy or health care provider. All aspects of reimbursement are defined by these contracts, including which, if any, benchmarks are used to set rates, how the benchmarks are applied, and from what source they are obtained. The result is wide variation from payor to payor, and even from contract to contract, in the manner and extent to which benchmarks factor in to the actual reimbursement paid for any given drug.

As a result, underlying each drug reimbursement are multiple contractual negotiations, each of which varies depending on the parties to be reimbursed and their particular objectives.

There are five types of contracts that determine net reimbursement for pharmaceuticals. Contracts between



employers and insurers for the provision of health care benefits, contracts between insurers and PBMs for the provision of pharmacy benefit management services, contracts between insurers or PBMs and pharmacies for dispensing pharmaceuticals, contracts between insurers and physicians for dispensing pharmaceuticals in the physician's office, and contracts between insurers or PBMs and manufacturers for preferred formulary positions. We'll discuss each of these in turn.

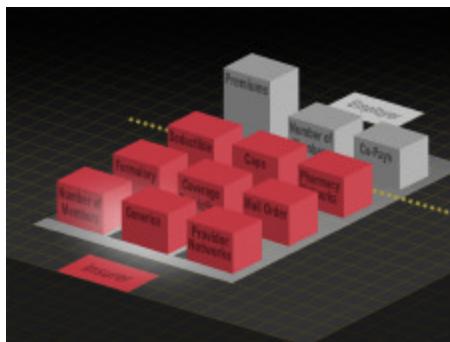
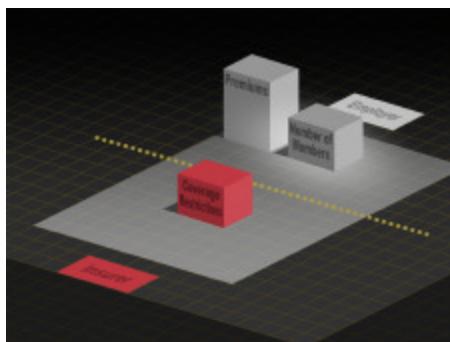
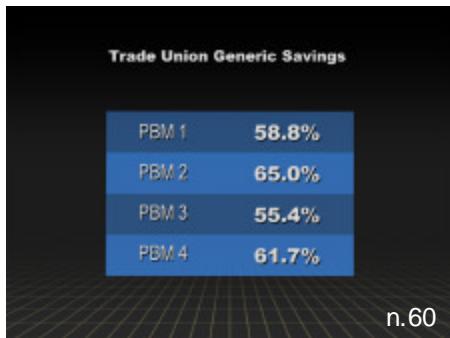
C. Contracts between Employers and Insurers

First are contracts between employers and insurers for the provision of pharmaceutical benefits. These contracts determine the premiums that employers and employees have to pay, and the co-payments or co-insurance required from employees for access to pharmacy benefits.

Employers must make a decision whether to self-insure or to pay for insurance.

If the employer determines that it might obtain insurance from a third party, then the employer starts a competitive bidding process by issuing RFPs (Requests for Proposals) to get bids from insurers competing to offer health benefits to the employees.

The requirements set forth in these RFPs are often developed with the assistance of professional benefits consultants, to reflect the objectives and interests of the employer. These benefits consultants, including major firms such as Segal Company, Towers Perrin and Mercer, also assist the employer in the evaluation of the proposals. This table shows a number of the benefit consultants, including Segal and Towers Perrin, that



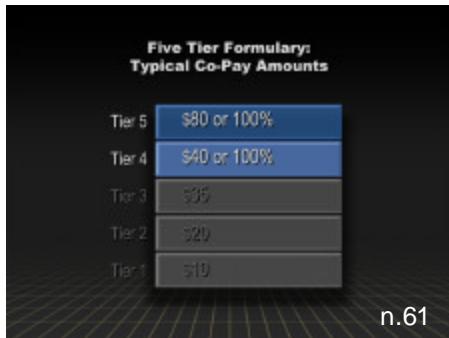
have recently assisted some of the employers and other plan sponsors involved in this case.⁵⁹

As one would expect, the responses to an RFP can vary widely. For instance, this table shows the range of reimbursement rates offered by four PBMs responding to the same trade union's RFP.⁶⁰ Note the broad variation in the promised reduction in spending on generic products; savings between 55.4% and 65% are promised on the plan's use of generic pharmaceuticals. Insurers often submit multiple responses to an RFP, giving a range of plan options for the employer. Employers in turn may offer several different plans to their employees.

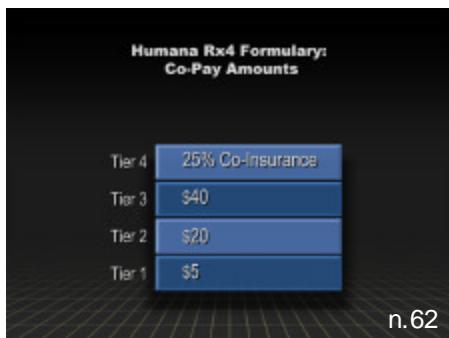
Contracts between employers and insurers can vary greatly both in the elements they include as well as the terms agreed to. For instance: How much the employer (and its members) must pay in premiums is weighed against the insurer's restrictions and limitations on coverage. The employer's size is considered – meaning how many paying members it brings to the table. The insurer's size, that is, the number of members it insures, as well as the size and composition of its pharmacy and provider networks, are also considered. Issues such as: the premiums to be paid by both the employer and the employee; deductibles and caps; co-payments and co-insurance; formulary tiers for pharmaceuticals; restrictions and limitations on coverage; use of mail order and generics; and other issues all combine to form unique contracts that vary from agreement to agreement.

⁵⁹ Young declaration, Exhibit 10.

⁶⁰ Ibid, Exhibit 12a.

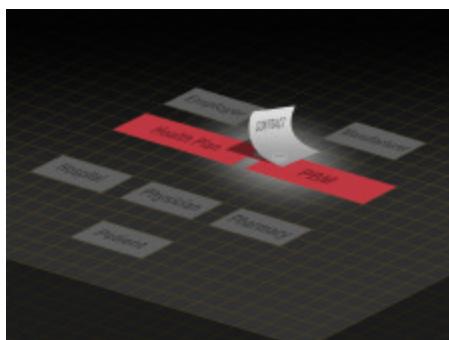


Note that for the employees using self-administered products, most co-payment requirements make no reference to AWP. As we discussed earlier, payment at the drug store is usually via a fixed co-payment that depends on the formulary being used by the insurer, with different co-payments for drugs on different tiers of the formulary. Today, some formularies have as many as 5 tiers, with a wide variety of typical co-pay levels, as you see illustrated here.⁶¹ Note that the upper tiers may require a measure of co-insurance that may be based on AWP. For instance, Humana offers a plan with a four-tier formulary with \$5, \$20 and \$40 co-payments for the first three tiers, plus a fourth tier requiring 25% co-insurance.⁶²



D. Contracts between Insurers and PBMs

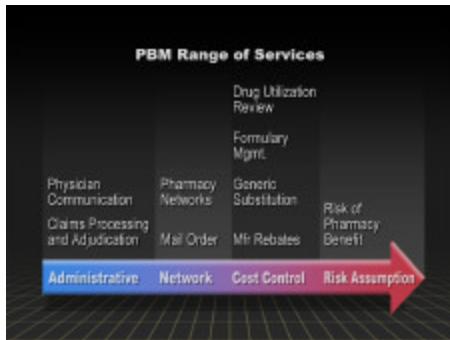
Now, once an insurer is committed to providing medical and pharmaceutical benefits, the insurer needs to contract with hospitals, physicians, pharmacies and other providers of health care services in order to provide those benefits. So, a second type of contract governing the reimbursement of pharmaceuticals for those insured by commercial plans may involve contracts between insurers, including those who self-insure, and PBMs for the management of pharmaceutical benefits.



These contracts determine which services the PBM will supply for the insurer and at what price. As discussed earlier, PBMs offer a broad range of services, from simple claims processing to assuming the risk of pharmacy benefits coverage. Of course, some insurers opt to provide all of their own pharmacy benefits, from setting up and managing their own network of pharmacies

⁶¹ Verispan's Managed Care Profiling Solutions, cited by Formulary Journal (Advanstar, 2004), Drug and Formulary Trends, Vol. 39, August 2004, p. 405.

⁶² Humana Inc., *Plan Descriptions*, http://apps.humana.com/prescription_benefits_and_services/execreq.asp?processcode=1&srcsite=employer (accessed November 23, 2004).



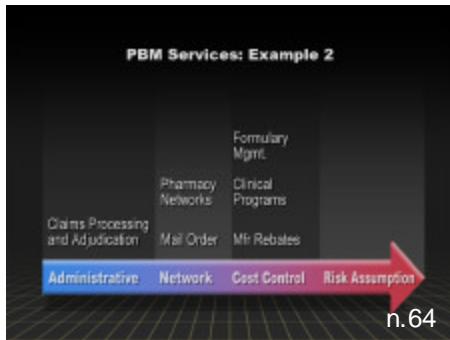
to dispense prescriptions, to designing their own formulary and negotiating rebates with manufacturers, to processing their own claims. Other insurers choose to contract with a PBM to assume some of these functions, and some insurers choose to contract with a PBM to provide all of these functions.

When PBMs emerged in the late 1980's, they were specialists in providing claims processing and adjudication, using advances in computer technology.⁶³ Over time, PBMs began to offer a variety of "value-added" services to their customers: pharmacy network administration; formulary design/management, including negotiating rebates with manufacturers; drug utilization review to see if a patient's different prescriptions might interact and cause side effects; physician communication and education, including formulary compliance incentives, mail order pharmacy services, generic substitution plans, and even the assumption of pharmacy risk.

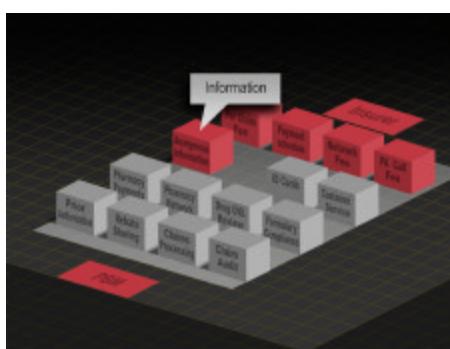
Payors can choose to purchase PBM services from a third party, or to self-supply the service, as Aetna, Anthem and Cigna do. Firms only purchase PBM services from third parties if it is more efficient for them to do so.

When an insurer sets out to choose an external PBM to manage its drug benefit, competitive bidding by PBMs is the norm. The insurer issues a request for proposals and then evaluates competing bids based on their particular criteria. Insurers negotiate vigorously to obtain the best possible financial and benefit package from the PBM and often retain the ability to offer the service themselves.

⁶³ *Deposition of Carol Sidwell*, September 17, 2004, pp. 64-65, as cited in *Young declaration*, paragraph 49.



The PBM services provided to any insurer depend upon the negotiation between that insurer and the PBM. For example, one large health plan requires only claims processing, formulary management, and mail order pharmacy services from their PBM. On the other hand, this union group contracted with their PBM for all of the above plus clinical programs, rebate negotiation, and preferred pharmacy provider networks.⁶⁴

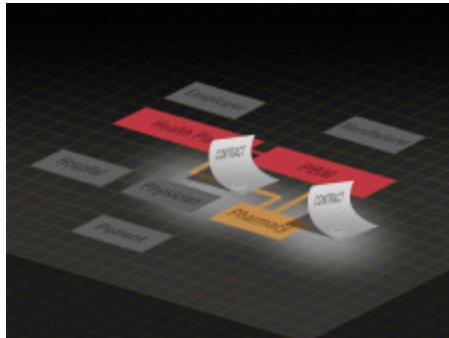


Thus, contracts between insurers and PBMs vary, specifying the services to be performed, the payments to be made, and the information to be shared.

E. Contracts between Payors and Pharmacies

To deliver pharmacy benefits, the insurer or PBM needs a network of pharmacies that will agree to dispense prescriptions to plan members. This is the third type of contract – that between the pharmacies and the PBM or insurer.

⁶⁴ Contracts JDH 001611 and MU 1807.

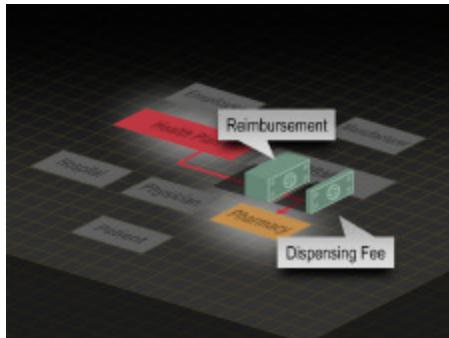


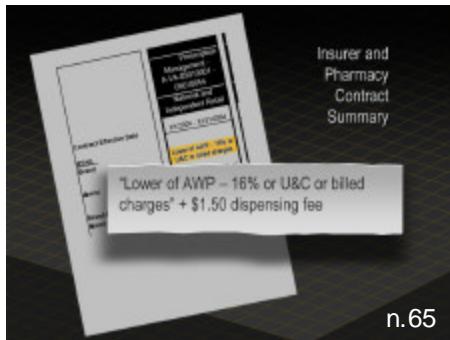
In some cases, such as a staff model HMO like Kaiser Permanente, the payor owns the pharmacies where members get prescriptions filled. In all other cases, though, the relationship between the insurer or PBM and the pharmacy is defined by a contract which details how much will be reimbursed for each type of drug.

Reimbursements to pharmacies typically include:

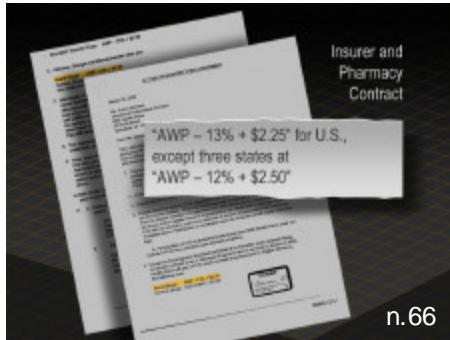
- Negotiated reimbursement for the pharmaceutical
- Negotiated dispensing and administrative fees per transaction

The pharmacy leverages its size and position in the market for better reimbursement rates, while the PBM or insurer keeps costs down with the guarantee of its membership's business.



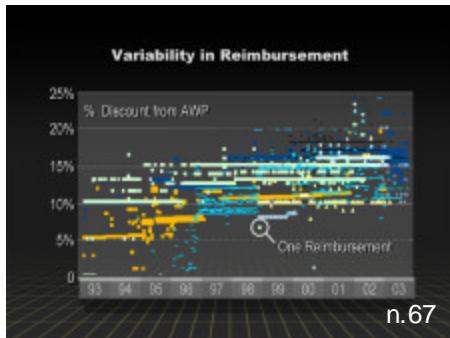


For branded products, reimbursement is typically based on a formula that defines the reimbursement amount as the lesser of a number of amounts, net of the appropriate co-pay. One of these amounts is usually expressed as a discount from a specific drug's AWP. For instance, in this case, reimbursement is based on the lower of 1) AWP minus 16%, or 2) usual and customary charges for the product, which can vary geographically, or 3) the pharmacy's billed charges, plus a \$1.50 dispensing fee.⁶⁵ There is complexity and variability in the contracts between payors and pharmacies. For instance, for the five different types of plans managed by this insurer, branded products are reimbursed differently in each. As another example, in this instance, reimbursement was based on geography, AWP minus 13% plus a fee of \$2.25 per transaction for all U.S. states but three, for which reimbursement was negotiated to be AWP minus 12% plus a fee of \$2.50.⁶⁶

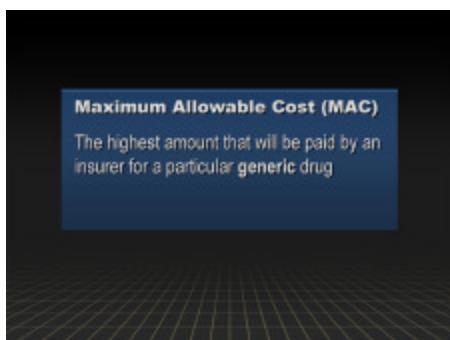


⁶⁵ Young declaration, Exhibit 12c.

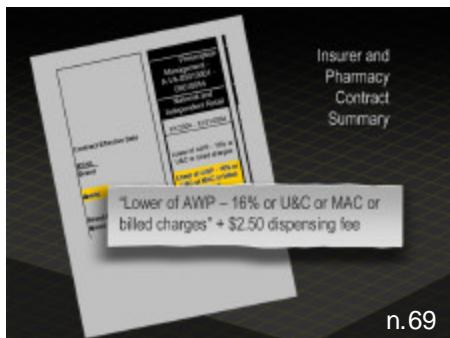
⁶⁶ *Idem.*



Note that the same pharmacy may be bound by different contracts with different insurers regarding different reimbursement calculations for both ingredient and dispensing costs and different co-payment requirements all for the same product over time as it serves its customers. This graph shows the variability of actual reimbursements for a specific drug by a range of payors, relative to AWP.⁶⁷



For generic products, reimbursement is also typically based on a formula that defines the reimbursement amount as the lesser of a number of variables. In these instances, Maximum Allowable Cost or MAC, which is generally lower than AWP, is commonly used.⁶⁸ For instance, for the same contract noted above, reimbursement for generic products is based on the lower of 1) AWP minus 16%, 2) usual and customary charges for the product, 3) MAC, or 4) the pharmacy's billed charges, plus a \$2.50 dispensing fee.⁶⁹



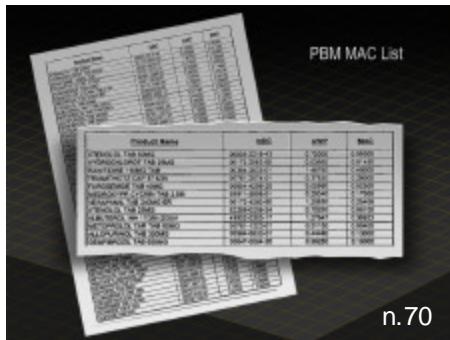
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⁶⁷ Declaration of Eric M. Gaier in Support of Defendant's Action Against Class Certification ("Gaier declaration"), October 25, 2004, Figure 21, p. 90.

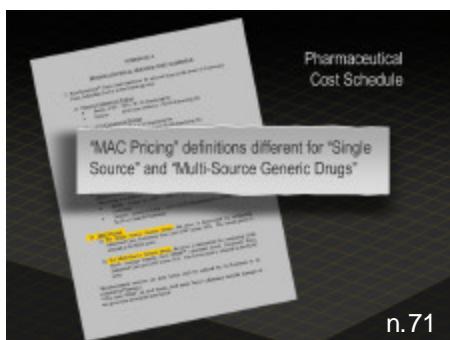
⁶⁸ Pharmacy Benefit Management Institute, *PBM News*,

<http://www.pbmi.com/pbmnews/v4n2.qa.htm> (accessed November 30, 2004).

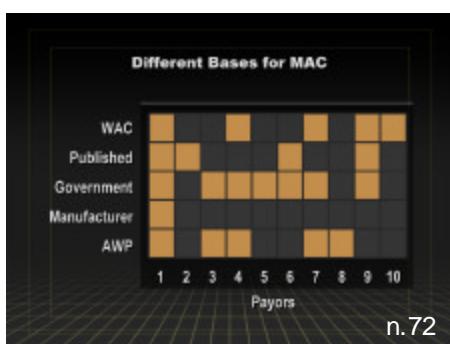
⁶⁹ Young declaration, Exhibit 12c.



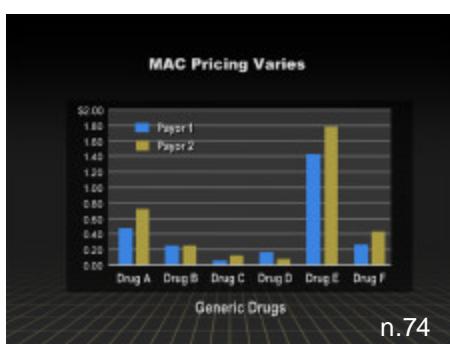
n.70



n.71



n.72



n.74

There is no established standard or consistent manner by which MACs are calculated. MAC lists are established by insurers, or by PBMs on their behalf, based on their own formulas. Here you see a sample list of one PBM's MAC prices.⁷⁰

Some of the contracts that reference MAC also define how it will be set; some do not. The determination of MAC may or may not take AWP into consideration, but when it is considered, it is one among several factors that are taken into account in setting the MAC price. Here we see that the definition of MAC depends on whether there was one or more generic products available. To the extent AWP could be used, there will first be a comparison of AWP minus 30%, if there is only one generic, or AWP minus 51%, if there are multiple generics, to the two to four other pricing alternatives.⁷¹ Here, one PBM uses WAC, not AWP, as a basis for its MAC price. In another instance, a health plan relies on the federal government to set its MAC prices.⁷² The federal government defines and calculates a Federal Upper Limit, or FUL, for generic drugs. The FUL is 150% of the lowest published price of all versions of a generic drug.⁷³ The FUL, published when at least three versions of a drug are on the market, is updated quarterly.

Given the different methodologies that insurers and PBMs could use to calculate MACs, it is no surprise that MAC prices could vary widely, as shown here.⁷⁴

⁷⁰ Proposal for PBM Services, p. 8, UFCW 02381-411

⁷¹ Contract, UPMC 002351-368.

⁷² *Gaier declaration*, Exhibit N, pp.129-130.

⁷³ CMS, *State Medicaid Manual*, Part 6, Addendum A, <http://www.cms.hhs.gov/manuals/pub45pdf/smm6t.pdf> (accessed November 22, 2004).

⁷⁴ MAC list from INH (INH AWP 000060-093) and MAC list form IHC (IHC AWP 000001-232).

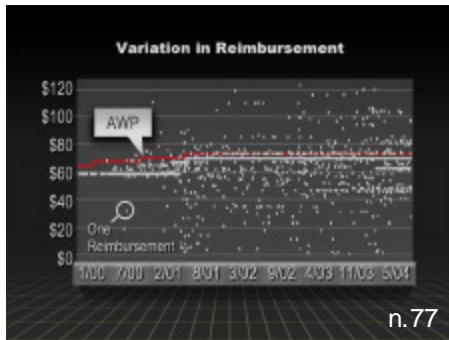
F. Contracts between Insurers and Physicians

The fourth type of contract is between the insurer and the physician for drugs dispensed in the physician's office. The insurer often provides this coverage under the medical benefits section of the health care plan, but not always. In a growing number of situations, certain drugs that are dispensed in the physician's office are being moved from medical benefit status to pharmaceutical benefit status. Procrit is one example. To provide medical benefits, the insurer must engage a network of physicians. The PBM generally does not play a role in these negotiations.

Once again, in the case of a staff model HMO, the physicians are employees of the payor. All other payors must enter contractual negotiations with physicians to establish reimbursement rates for medical services provided. Prescription drugs have historically comprised a small component of the overall reimbursement dollars paid to physicians, but this varies by specialty.⁷⁵ Often, prescription drug reimbursement rates are bundled within overall fee schedules.

In any negotiation with insurers, the physician considers the direct cost of providing the medical services, but also the indirect costs associated with operating his business. Payors and physicians usually negotiate for the overall fee schedule for all services and drugs provided by the physician, and agree to the individual element pricing to achieve that overall fee schedule. Individual element pricing is often based on convenient benchmarks, such as AWP.

⁷⁵ See data from the Federal Register, Vol. 69, No. 4, p. 1109, Table 11.



Even where the ultimate agreement makes reference to AWP, the amount actually reimbursed to physicians is usually the lesser of an amount listed on the physician fee schedule or other limitations, including the “usual and customary” amounts and the physician’s “charged” or “billed” amount.

Actual negotiated reimbursement rates depend on many factors, including competition, size, market share, specialty and geographic location, among others.⁷⁶ For example, large physician groups could negotiate higher reimbursement rates than small groups or independent physicians; and, physicians with little competition, for example in rural areas, could also negotiate higher reimbursement rates.

Formularies are less frequently used by insurers with respect to physician-administered drugs. Staff model HMOs, which can and often do have formularies for physician-administered drugs, are the exception.

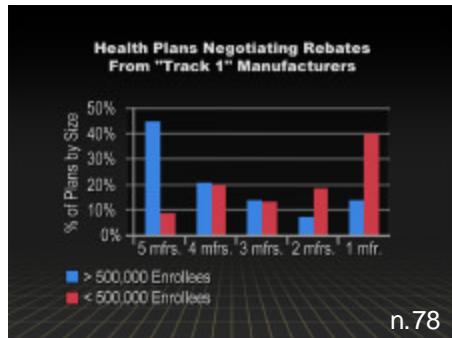
As you can see on this graph, the result of these negotiations is great variation in the actual amounts reimbursed, even by a single insurer for a specific drug.⁷⁷ Note that the red line on this scatter plot represents AWP.

G. Contracts between Payors and Manufacturers

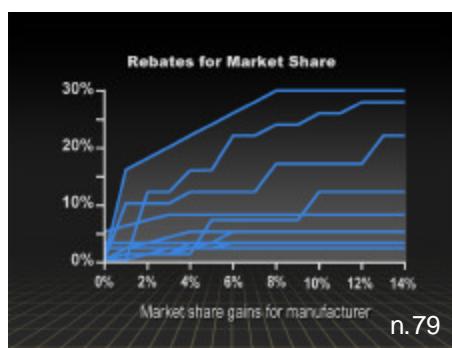
Finally, there are contracts between insurers, or their PBMs, and manufacturers for rebates. Insurers and PBMs extract these rebates from manufacturers in return for giving preferred formulary positions to the manufacturers’ products. Manufacturers of branded products with little or no competition in their therapeutic categories will typically pay small rebates, if any.

⁷⁶ *Young declaration*, paragraphs 145-146.

⁷⁷ *Young declaration*, Exhibit 15, graph 5.



Manufacturers of branded products in crowded therapeutic categories may use a preferred formulary position to help compete for prescription share. By controlling the formularies, insurers and PBMs can extract rebates from the manufacturers in return for formulary position, prior authorization requirements applied to competing products, physician education on behalf of the product, and so forth.



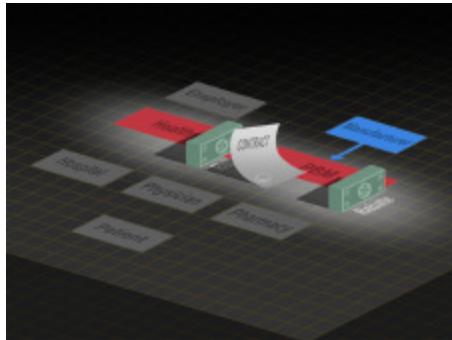
It is important to realize that it is not just PBMs who negotiate discounts and rebates with manufacturers. This graph depicts the contracting relationships of 90 insurers of all sizes with the five Track 1 manufacturers.⁷⁸ As shown, nearly 2/3 of the larger insurers have directly negotiated discounts and rebates with 4 or all 5 of the Track 1 manufacturers; and 60% of the smaller insurers have contracting relationships with more than 1 of the Track 1 manufacturers.

Rebates are typically based on performance of some kind and paid retrospectively, usually quarterly. Rebates can be based on volume; formulary position, for instance a listing on the second tier and whether or not competing products are listed on the same formulary tier; and share of prescriptions reimbursed in a therapeutic category. Rebates are often expressed as a percent of WAC and paid based on the prescription volume that the insurer or PBM reimburses.

This chart shows the range of actual rebates extracted for different levels of market share for each one of a manufacturer's products.⁷⁹ For the products confronting more competition from therapeutic substitutes, the rebate percentages are higher.

⁷⁸ *Ibid*, Exhibit 6b. Atlantic Information Service, *Directory of Health Plans*, 2004.

⁷⁹ Managed Care Group, *Retail Managed Formulary Rebates*, MDL- OMP 0004071-072.



The amount of the rebate that the insurer or the PBM is able to extract is typically driven by the potential volume of prescriptions at issue and the degree to which formulary measures are likely to influence both physician prescribing and patient fulfillment of the prescriptions.

Thus, branded self-administered drugs may be in different positions on different formularies at different times, based on a variety of contracts with different payors and PBMs performing to different degrees.

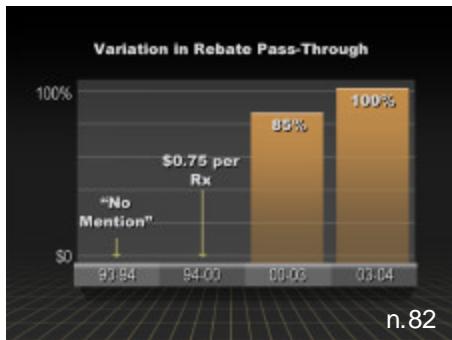
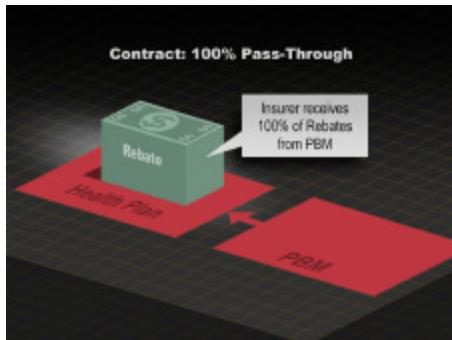
The rebates are paid to the entity that controls the formulary, whether a PBM or insurer. If a PBM controls the formulary, the extent to which the insurer is aware of the amount of the rebates and receives a share of the rebates depends on the relationship between the insurer and the PBM and the terms of the contract between the insurer and the PBM.

In some circumstances, the insurer uses a PBM but manages the formulary itself. That insurer would contract directly with the manufacturers for rebates, and would of course be well aware of the amounts.



Other insurers decide to outsource formulary management to the PBM. In some cases, the contract specifies a certain percentage of the rebates to be passed through to the insurer. All of the insurers on this chart received some level of rebate pass-through and that level varied based on the negotiation between the insurer and the PBM.⁸⁰ Nonetheless, knowing the amount of the rebates passed through and the pass-through percentage negotiated with their PBM, all of these insurers know exactly how much the rebates are and how much the insurer is paying to reimburse for the drug.

⁸⁰ *Gaier declaration*, Exhibit L.2, pp.116-120.



In other circumstances, perhaps in return for reduced fees up-front, or provision of other services by the PBM, the insurer may sign over all rebates to the PBM, in which case the insurer may not know the amount of rebates. An insurer's relationship with a PBM could evolve in a number of different ways. For instance, it may start out that the insurer is receiving all rebates as the manager of the formulary, then receiving only a share of the rebates as it cedes control of the formulary/rebate negotiations to the PBM, and finally, perhaps receiving no rebates at all as it chooses to pay a lower fee for the rest of the PBM's services.⁸¹ Alternatively, here is an example of progression in rebate pass-through as a health plan earns a progressively greater share of rebates.⁸²

Thus, the actual percentage of rebates retained by the PBM varies from contract to contract, depending on the specific agreement between the PBM and each insurer customer.

⁸¹ 2000 government study estimated that PBMs pass on to their insurer customers about 70 to 90 percent of the rebates they receive from manufacturers. U.S. Department of Health and Human Services, "Report to the President: Prescription Drug Coverage, Spending, Utilization and Prices at Chapter 3, available at

⁸² *Gaier declaration*, Appendix J.

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser Gross Margin	Retail
Reimbursement	108
Net acquisition cost	100
Gross margin	8

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser Gross Margin	Retail
Reimbursement	108
Net acquisition cost	100
Gross margin	8
Manufacturer Net Proceeds	
Initial sale	100
Price concessions	20
Net proceeds	80

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (100% PBM pass-through)	20
Net insurer reimbursement	88
Spread	-12

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (100% PBM pass-through)	20
Net insurer reimbursement	88
Spread	-12

H. Impact of PBM Rebate Pass-through on Spread

Finally, let's revisit the spread calculation that we discussed back in Section II of the tutorial [see Appendix-Exhibit 3]. Except this time, let's consider another of the factors that can affect the spread, namely the situation where a PBM has been contracted by the insurer to provide some measure of formulary management services. Based on the extent of the services being provided, the PBM might be required to pass-through all, half, or none of the manufacturer rebates received.

The net acquisition cost to the pharmacy for the product at issue we'll assume is still \$100. The insurer still reimburses the pharmacy at AWP minus 10%, or \$108, so the pharmacy's gross margin remains at \$8.

And, the manufacturer still makes a price concession of \$20, in the form of a rebate to the payor, keeping their net proceeds at \$80.

However, in this case, the rebate goes to a PBM. If the PBM passes all of the rebate through to the insurer, there is no change from the original net reimbursement cost of \$88. From the insurer's perspective, the spread, the difference between its net reimbursement cost and the dispenser's net acquisition cost, is still negative \$12. It is still the case that the insurer (including the patient co-pay) is reimbursing for less than the dispenser's net acquisition cost.

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (50% PBM pass-through)	10
Net insurer reimbursement	98
Spread	-2

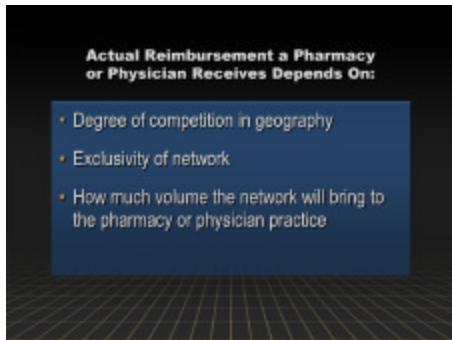
Next, consider a case where the insurer, perhaps in return for more services from the PBM, negotiates with the PBM to receive only 50% of the rebates collected by the PBM. In this case, the insurer would receive only \$10 of the rebate. So, from the insurer's perspective, net reimbursement is \$98 and the spread is still negative by \$2.

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (50% PBM pass-through)	10
Net insurer reimbursement	98
Spread	-2

Now, consider a case where the insurer assigns the full responsibility for the pharmacy benefit to the PBM. In this case, from the insurer's perspective, net reimbursement is \$108 and the spread is \$8. The PBM has pocketed the manufacturer's rebate as one element of the compensation for managing the insurer's benefit. But, as a result, the PBM is able to offer the insurer a full suite of pharmacy benefit management services for a lower price, based on the expected amount of manufacturer rebates that the PBM would collect.

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (0% PBM pass-through)	0
Net insurer reimbursement	108
Spread	8

Spread Example: PBM Pass-Through of Manufacturer Rebates	
Dispenser	Retail
Acquisition cost	100
Mfr discount	0
Net acquisition cost	100
Insurer	
Reimbursement	108
Mfr rebate (0% PBM pass-through)	0
Net insurer reimbursement	108
Spread	8



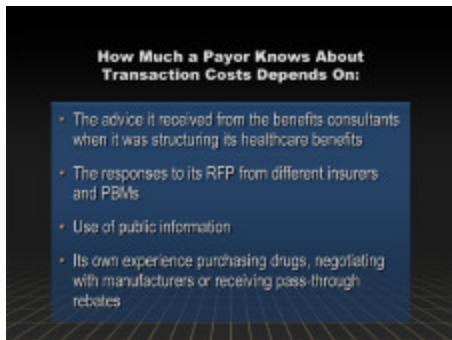
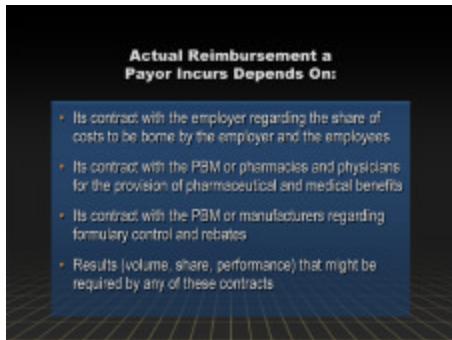
I. Summary

To summarize, underlying each drug purchase are multiple contractual negotiations affecting net reimbursement, each of which varies depending on the parties to be reimbursed and their particular objectives.

The actual reimbursement a pharmacy or physician receives depends on its contract with the insurer or PBM; and that depends upon the negotiation between the insurer or PBM and the pharmacy or physician. This negotiation will consider:

- the degree of competition faced by the pharmacy or physician group in the geography they operate
- the exclusive nature of the insurer's or PBM's network;
- and, how significant the insurer's or PBM's network is likely to be in terms of total volume to the pharmacy or physician practice.

As a pharmacy or physician, I might be willing to accept a lower reimbursement rate if I knew that I were becoming part of a network that services a large number of potential patients, and that I expected to realize a large share of those potential patients. On the other hand, if I'm the only pharmacy or physician practice around, I'm likely to demand a premium for my services from a health plan that wishes to offer comprehensive coverage to its members.



The net reimbursement cost an insurer incurs depends on:

- its contract with the employer regarding the share of costs to be borne by the employer and the employees;
- its contract with the PBM or directly with the pharmacies and physicians for the provision of pharmaceutical and medical benefits;
- its contract with the PBM or directly with the manufacturers regarding formulary control and rebates;
- and, the results achieved with respect to contracted volumes, share, performance, etc., that might be required by any of these contracts.

Further, the terms in each of these contracts are negotiated based upon the objectives, expectations, and desires of the parties involved.

Finally, however much any employer or ultimate payor knows about the cost it bears as a result of each pharmaceutical transaction depends on many factors:

- the advice it received from the benefits consultants when it was structuring its health care benefits;
- the responses to its RFP from different insurers and PBMs;
- use of public information;
- and its own experience, including:
 - whether it also acts as a direct purchaser of drugs, and therefore negotiates its own discounts; and
 - whether it negotiates for manufacturer rebates itself, or, if through a PBM, whether the PBM shares information about the level of rebates it obtains.

In closing, it's important to keep in mind that the transactions which comprise acquisition and reimbursement in the



pharmaceutical industry, particularly in the commercial setting, are characterized by:

- complex negotiations between multiple entities, each with their own objectives;
- competitiveness at each level of the chain;
- multiple factors impacting outcomes; and
- availability of information for parties to use as the basis of their negotiations.

Whether or not AWP is used as a reference point to determine reimbursement amounts for certain transactions depends upon the transaction, the parties involved, and the context of any negotiations between those parties regarding the reimbursement of pharmaceuticals.

The result is an almost endless number of ways in which these elements can be combined or applied, ensuring that each resulting contract is virtually unique, with a wide range of consequences for net acquisition cost, net reimbursement cost, and spread.

Appendix

Exhibit 1**Spread Example: Branded Drug, No Price Concessions**Dispenser

Acquisition cost (WAC)	100
Mfr discount	0
Net acquisition cost	<u>100</u>

Insurer

Reimbursement (AWP-10%)*	108
Mfr rebate (to insurer)	0
Net reimbursement	<u>108</u>

SPREAD**8**Dispenser Gross Margin

Reimbursement	108
Net acquisition cost	100
Gross Margin	<u>8</u>

Manufacturer Net Proceeds

Initial sale	100
Price concessions	0
Net proceeds	<u>100</u>

* AWP = \$120

Exhibit 2**Spread Example: Branded Drug, \$20 Manufacturer Price Concession**

	\$20 Mfr.	\$20 Mfr.
	Rebate	Discount
	Retail	Physician
<u>Dispenser</u>		
Acquisition cost (WAC)	100	100
Mfr discount	0	20
Net acquisition cost	<u>100</u>	<u>80</u>
<u>Insurer</u>		
Reimbursement (AWP-10%)*	108	108
Mfr rebate (to insurer)	20	0
Net reimbursement	<u>88</u>	<u>108</u>
SPREAD	<u>-12</u>	<u>28</u>
<u>Dispenser Gross Margin</u>		
Reimbursement	108	108
Net acquisition cost	<u>100</u>	<u>80</u>
Gross Margin	<u>8</u>	<u>28</u>
<u>Manufacturer Net Proceeds</u>		
Initial sale	100	100
Rebate	20	20
Net proceeds	<u>80</u>	<u>80</u>

* AWP = \$120

Exhibit 3**Spread Example: PBM Pass-Through of Manufacturer Rebates**

		\$20 Mfr. Rebate		
		Retail		
		% Pass-Through		
		100%	50%	0%
<u>Dispenser</u>				
Acquisition cost (WAC)		100	100	100
Mfr discount		0	0	0
Net acquisition cost		100	100	100
<u>Insurer</u>				
Reimbursement (AWP-10%)*		108	108	108
Mfr rebate (to insurer)		20	10	0
Net reimbursement		88	98	108
SPREAD		-12	-2	8
<u>Dispenser Gross Margin</u>				
Reimbursement		108	108	108
Net acquisition cost		100	100	100
Gross Margin		8	8	8
<u>Manufacturer Net Proceeds</u>				
Initial sale		100	100	100
Rebate		20	20	20
Net proceeds		80	80	80

* AWP = \$120